OPERATIONAL ISSUES OF HEALTH
PUBLIC-PRIVATE PARTNERSHIPS

Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

Zambia

Initiative on
Public-Private
Partnerships
for Health

ALLEVIATING THE HEALTH CONSEQUENCES OF
POVERTY BY ENHANCING PUBLIC-PRIVATE COLLABORATION

Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

ZAMBIA

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Initiative on Public-Private Partnerships for Health

Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Zambia

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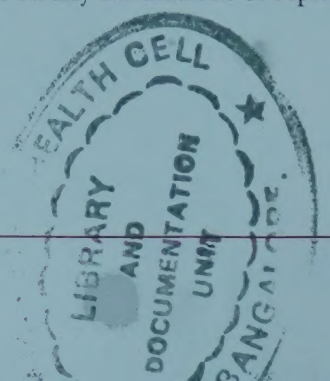

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Foreword

by Roy Widdus, Ph.D.
Project Manager, Initiative on Public-Private Partnerships for Health
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The study described in this report is one of a series initiated and designed by the Initiative on Public-Private Partnerships for Health (IPPPH), supported principally by the UK Department for International Development, and undertaken in association with the Institute for Health Sector Development based in London. The series also includes country studies on Uganda (the pilot country studied in 2003), Botswana and Sri Lanka. A 'synthesis report' covers conclusions and recommendations across all countries and programmes evaluated.

IPPPH was established in 2000, in part to develop a solid evidence base on public-private 'partnerships' for health so that the benefits of such collaboration for populations afflicted by poverty could be maximized and potential risks ameliorated.

IPPPH identified early in its existence the need for the type of study described in this report in response to a range of questions being raised about 'partnerships' addressing drug access in low- and middle-income countries that included donations or discounted pricing from pharmaceutical companies. Funding was provided by the UK Department for International Development (DFID) with supplementary support from the general contributors to IPPPH, namely, the Bill & Melinda Gates Foundation, the Global Forum for Health Research, The Rockefeller Foundation, and the World Bank.

The study design benefited from wide input, including staff of the World Health Organization and the Study Advisory Committee. A team of consultants was selected with assistance from the Institute for Health Sector Development, London, an organization specializing in evaluation of health systems issues in developing countries. Ultimate approval of the study protocol rested necessarily with the IPPPH as the agent responsible to the principal funder, DFID, along with the national government counterpart.

All members of the consultant team are independent of the pharmaceutical industry and IPPPH. None of the national consultants had any direct programmatic or managerial responsibility for any of the programmes examined. However, their knowledge of the national health system and key information sources greatly benefited the study.

The IPPPH Secretariat, along with the Study Advisory Committee, offered suggestions for clarification of the draft text of the report and is pleased to publish the consultant team's final report in its entirety, as a significant contribution to understanding the actual impact at national and field level of these diverse collaborative ventures.

This study can stand alone, but is part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access to pharmaceuticals for those affected by diseases associated with poverty. However, as noted above, it is part of a series undertaken to serve this general goal. Readers should consult the 'synthesis report'[1] for general conclusions on those issues addressed in this series of studies. This series of studies adds considerably to the evidence base on 'access' public-private partnerships but further issues need to be considered. The foreward to the synthesis report identifies some programmes and issues that this series of studies could not cover.

IPPPH thanks the UK Department for International Development for its financial support, and the excellent consultant team, comprising: Qhing Qhing Dlamini, health development consultant, Swaziland – who deserves credit as team leader for the study – Louisiana Lush, senior lecturer, Health Policy of the London School of Hygiene and Tropi-

[1] Impact of Public-Private Partnerships addressing access to pharmaceuticals in selected low-income and middle-income countries: A synthesis report from studies in Botswana, Sri Lanka, Uganda and Zambia; ISBN 2-940286-21-3

cal Medicine, United Kingdom; Martin Auton, independent consultant on the management of medicines in public health, South Africa; and Patrick Nkandu, health consultant, Zambia.

Special thanks must go to the many individuals in Zambia who gave generously of their time to the consultant team. We trust the insights of the study, especially into areas needing more external technical and financial assistance, will prove useful to them, as well as the broader international community.

Abbreviations

AAI	Accelerating Access Initiative
ACT	Artemisinin combination therapy
AED	Academy for Educational Development
AIM	African Initiative on Malaria
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
BHCP	Basic health care package
CBOH	Central Board of Health
CCM	Country Coordinating Mechanism
CHAZ	Churches Health Association of Zambia
CIDRZ	Centre for Infectious Disease Research in Zambia
CQ	Chloroquine
DALYs	Disability adjusted life years
DHMT	District Health Management Team
DFID	(UK) Department for International Development
EDL	Essential drugs list
GAEL	Global Alliance to Eliminate Leprosy
GFATM	Global Fund to Fight AIDS, TB and Malaria
HC	Health centre
HDI	Human Development Index
HIPC	Highly indebted poor countries
HMIS	Health Management Information System
HQ	Headquarters
IMCI	Integrated Management of Childhood Illness
IPPPH	Initiative on Public-Private Partnerships for Health
ITNs	Insecticide treated nets
LF	Lymphatic filariasis
MCH	Maternal and child health
MDT	Multi-drug therapy (leprosy)
MOH	Ministry of Health
MSF	Médecins Sans Frontières
MSL	Medical Stores Limited
NAC	National HIV/AIDS/STD/TB Council
NDP	National Drug Policy
NGO	Non-governmental organization
NFSD	Novartis Foundation for Sustainable Development
NLRI	Netherlands Leprosy Relief International
NMCC	National Malaria Control Centre
NMCP	National Malaria Control and Prevention Programme
OPD	Out-patients department
PEPFAR	(US) President's Emergency Plan for AIDS Relief
PHMT	Provincial Health Management Team
PHA	People living with HIV and AIDS
PMTCT	Prevention of mother-to-child transmission
PPP	Public-private partnership
PRSP	Poverty Reduction Strategy Paper
PSI	Population Services International
PSZ	Pharmaceutical Society of Zambia
RBM	Roll Back Malaria
RPM Plus	Rational Pharmaceutical Management Plus Programme (USAID funded)
SFH	Society for Family Health
SP	Sulphadoxine-pyrimethamine
TB	Tuberculosis
TDRC	Tropical Disease Research Centre
TLMI	The Leprosy Mission International
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
UTH	University Teaching Hospital
VCT	Voluntary Counselling and Testing
WHO	World Health Organization
WR	WHO Representative
ZDHS	Zambia Demographic and Health Survey

Executive summary

The UK Department for International Development (DFID) funded the Initiative for Public-Private Partnership for Health (IPPPH) to conduct a study in Zambia to assess the health and health systems impact of public-private partnerships (PPPs) for improving access to pharmaceuticals in relation to tropical diseases (malaria and leprosy) and HIV/AIDS (prevention of mother-to-child transmission (PMTCT) and prevention and treatment of opportunistic infections (OIs). The specific remit was to examine issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured. The key research question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor.

The study was rapid and largely qualitative, making extensive use of semi-structured interviews with key informants at national and district levels. The fieldwork was undertaken during a two-week visit by three international consultants and one national consultant in March 2004. Field visits were made to four districts in Zambia – Chibombo, Lusaka, Mpika and Ndola – selected on the basis of active implementation of PPPs; provincial and socio-economic representation; and accessibility within the timescale of the study. The study ensured that each PPP was visited in at least one district. The malaria (Coartem®) PPP was reviewed in Chibombo, Lusaka and Mpika districts, the leprosy PPP in Chibombo, Lusaka, Mpika and Ndola districts, and the HIV/AIDS PPPs in Lusaka and Ndola districts. All members of the study team are independent of the IPPPH and the pharmaceutical industry.

Tropical disease PPPs: malaria and leprosy

Governance of, and decision-making within, both the PPP-assisted national tropical disease programmes rests at national level, and complies with the criteria agreed by the overarching global health partnerships for leprosy and malaria. The study found no evidence of unreasonable conditionalities for these two tropical disease drug access PPPs in relation to the scope of the programme, drug indications or modes of operation.

Malaria

Malaria is a serious public health problem in Zambia. In November 2001, with support from WHO Roll Back Malaria (RBM), the Ministry of Health (MOH) and Central Board of Health (CBOH) decided to shift from chloroquine to artemisin-based combination therapy artemether-lumefantrine (Coartem®) as the first-line drug for treating uncomplicated malaria. This policy change was a response to the high resistance to chloroquine (CQ) and emerging resistance to sulphadoxine-pyrimethamine.

The Coartem® programme is currently supported by Novartis and the Global Fund to Fight AIDS, TB and Malaria (GFATM), with ongoing technical support from WHO RBM. Governmental commitment to the Coartem® PPP is high in Zambia, despite reported concerns among some donors about the relatively high cost of the drug and sustainability. Novartis' discounted price under the PPP is US$ 2.40 per adult treatment, compared with a private sector price in Zambia of US$ 12.00. However, even the discounted price is still relatively expensive compared with the superseded (because no longer effective) policy of chloroquine treatment which was inexpensive at US$ 0.20 per treatment.

- The Coartem® programme was introduced in early 2003, and is being implemented in 28 pilot

districts. It is therefore relatively early to assess overall health and health systems impact, although there are signs that community awareness and demand for treatment with Coartem® are growing rapidly. Plans, as set out in the GFATM proposal, to expand coverage to all 72 districts by end 2004 are felt to be ambitious and may pose logistical challenges. As scaling up takes place, it will be important to monitor access by lower income groups to ensure that they are benefiting from the new treatment.

- Coartem® is procured for Zambia by WHO, with funds from the GFATM. Early problems with distribution to secondary and mission hospitals have been resolved, now that the initial vertical drug management and distribution system set up for Coartem® has been fully integrated into the mainstream drug distribution system and health management information system. A key challenge will be to ensure a constant supply of Coartem® as the programme is scaled up.

- Staff at national and district levels perceive that the Coartem® initiative has the potential to benefit patients with chloroquine-resistant malaria and to strengthen health system capacity in pharmacovigilance. Given its high cost, the introduction of Coartem® has also motivated the MOH to improve prevention and diagnostic aspects of malaria control. Novartis also plans to provide support to Zambia's malaria capacity building programme, in relation to training, communications and research, at an estimated cost of US$ 2.2 million over three years from 2004.

- The discount programme specifies reasonable conditionalities, concerning Coartem®'s inclusion in treatment guidelines, effective distribution and facility reporting. Programme conditionalities also imply that repeated product diversion to unauthorised private providers could result in product withdrawal, although it is too early to assess how any diversion incidents will be addressed in practice. Given its high cost, and growing demand, there is a clearly a risk of diversion of Coartem® to the private sector. Stocks in public facilities and authorised private pharmacies will need to be monitored carefully, and anti-diversion measures may need to be strengthened.

- In light of the estimated 50-60% of patients who seek malaria treatment from the private sector, the PPP discount price will also be available to authorised private providers. CBOH has decided, with the agreement of WHO and Novartis, to implement an innovative pilot social marketing programme in partnership with the private sector. This initiative is an important step and will provide valuable lessons for scaling up access in both Zambia and other countries.

- Zambia would have difficulties in financing provision of Coartem®, in the absence of significant price discounts and the new source of finance provided by the GFATM. Both the GFATM and WHO have provided support to Zambia in making the policy shift. With the approval of Zambia's fourth round application, grants from GFATM are likely to sustain Coartem® procurements for the next three to five years. To ensure sustainability in the medium and longer term, the inclusion of Coartem® requirements in the national health budget is recommended.

- The study suggests that a review in due course to draw on greater experience at country level of the Coartem® discounted price agreement for malaria could be of benefit, since it potentially raises significantly different issues from the drug donation PPPs, in relation to affordability, market impact and sustainability. Novartis' planned capacity building inputs in training, education and operational research will also be important to evaluate, in terms of lessons learnt for PPP involvement in health system strengthening activities.

Leprosy

There has been a long-standing leprosy control programme in Zambia, dating back as far as 1932. Multi Drug Therapy (MDT) was introduced in some areas in 1986, and there has been national coverage since 1991. A WHO evaluation confirmed that Zambia achieved elimination at national level in 1999, against WHO definition of elimination as less than one case per 10,000 population. Only two provinces out of nine – Western and Luapula – had not reached elimination levels by 2000. Remaining pockets of higher prevalence are attributed to refugee migration from neighbouring countries in conflict. The challenge now is to secure progress in reducing prevalence in these areas.

- While the supply of donated MDT through the Novartis-WHO PPP remains an important contribution, national coverage with MDT had been achieved prior to the initiation of the WHO-Novartis agreement in 1999.

■ The programme is fully integrated into general health care services, as part of a joint programme with TB. The MDT donation programme uses an adapted MOH and CBOH ordering system for all drugs purchased through WHO and the drugs are distributed through the mainstream drug distribution system.

■ There is no evidence of distortion of priorities, nor of the allocation of human or financial resources at district level. Sustainability is feasible, since leprosy is a comparatively small-scale problem and the national leprosy programme benefits from good collaboration between the CBOH and Churches Health Association of Zambia (CHAZ) as well as support from international donors.

Other tropical diseases

The study team found some indications that the availability of support from the range of drug access PPPs may not be as widely known as is desirable. With respect to other tropical diseases, a 2003 survey suggested that there were cases of lymphatic filariasis in three of the 16 districts surveyed. Further epidemiological investigation has been recommended to inform any future government decision on whether Zambia should apply for donated drugs for lymphatic filariasis. WHO has expressed interest in assisting the government to assess national prevalence of sleeping sickness, to determine whether an application for donated drugs is appropriate.

HIV/AIDS PPPs: Viramune® and Diflucan®

Zambia is experiencing a generalised HIV/AIDS epidemic. The government has set out strategies for prevention and treatment, including a target of 100,000 people living with HIV/AIDS on antiretroviral therapy (ART) by the end of 2005. The current per capita drug budget (including for antiretroviral drugs) is approximately US$ 3.50, and, while the government invested US$ 3 million in 2003 in procuring antiretroviral drugs (ARVs), the figure for 2004 may be lower due to fiscal constraints. The country is likely to benefit from new sources of external funds for treatment including the GFATM, World Bank Multisectoral AIDS Programme (MAP) and US President's Emergency Plan for AIDS Relief (PEPFAR), the latter of which in particular may mean greater volumes of originator products.

Zambia does not participate in the Accelerating Access Initiative (AAI), the UN-supported framework for accessing preferential prices for ARVs from major research and development companies. It currently procures its ARVs from generic sources. Zambia currently participates in two global PPPs related to HIV/AIDS, Boehringer Ingelheim's Viramune® Donation Programme and Pfizer's Diflucan® Partnership Programme. Prevention of mother-to-child transmission (PMTCT) and treatment of opportunistic infections (OIs) are priorities for the Zambian government.

■ The national PMTCT programme, launched in early 2003, covers 11 districts, mainly in urban areas, building on earlier pilot project sites run by partners including UNICEF, AED Linkages and the Columbia University Centre for Infectious Disease Research in Zambia (CIDRZ). The national programme aims to cover all 72 districts by the end of 2005, with 70% of pregnant women receiving voluntary counselling and testing services and 75% of HIV-positive mothers and their infants receiving prophylactic ART.

■ The Viramune® Donation Programme started to deliver drugs to the CBOH in May 2003, under a contract managed by Axios on behalf of Boehringer Ingelheim (BI), and BI intends to extend the donation programme beyond 2005. Prior to centralisation at CBOH, several PMTCT projects had independent contracts with BI at international level. A key challenge for the government programme has been incorporating and coordinating these disparate initiatives without disrupting their drug supplies, and parallel systems continue in some areas.

■ Integrating Viramune® distribution into the drug supply system has been complex, even with the support that has been provided to assist CBOH. The programme has substantial monthly reporting requirements as part of the drug requisition process, and a separate information system on demand, supply and impact is maintained since the HMIS is overstretched. However, the national programme manager maintains that the costs of reporting are more than offset by the savings on buying generic nevirapine on the open market, although this has not been quantified.

■ The programme is functioning fairly successfully, but has yet to scale up to national coverage. This will require improved cooperation between different stakeholders, including the different depart

ments within the CBOH and National HIV/AIDS/STI/TB Council PMTCT Technical Working Group, as well as strategies to reach women in rural areas who do not give birth in health facilities.

- PMTCT policy is evolving rapidly with the increased availability of ARV triple therapy, which may render single dose monotherapy for PMTCT inappropriate due to the potential for development of resistant strains. The PMTCT Technical Working Group is likely to recommend a policy shift to triple or dual therapy for PMTCT in the near future. This may have implications for the Viramune® Donation Programme, which may no longer be a priority unless nevirapine is used as a component of triple therapy and BI agrees to its donation being used in this way.

- The Diflucan® Partnership Programme offers a useful treatment for oesophageal candidiasis and life-long prophylactic maintenance of cryptococcal meningitis. Without the PPP, the drug might not otherwise be available, and the PPP is likely to remain a priority in Zambia. However, fluconazole is not the drug of choice for the acute phase of cryptococcal meningitis in Zambia – instead amphotericin B is recommended. Prescription of Diflucan® requires laboratory confirmation of the cryptococcal meningitis diagnosis. This is only available in tertiary facilities, thereby limiting the number of patients who can access treatment.

- Diflucan® is provided through two separate arrangements, with the CBOH and with CHAZ, but is distributed as part of the mainstream drug supply system. The programme requires the use of dedicated and quite complex drug management tools and reporting requirements that are beyond those required by the mainstream system. National ordering for the programme overall depends on being able to compile reports from all the 21 facilities currently receiving Diflucan®. If individual facility reporting is inadequate, this has implications for the national requisition process, which could result in stock outs and treatment interruptions. Efficient drug supply management will be an increasing challenge as the programme expands, and it is suggested that reporting requirements are reviewed to reduce their complexity.

1. Background and approach to the study

Background

The health consequences of poverty lead to major inequities in developing countries such as Zambia, and ill-health perpetuates poverty. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled independently by the public sector or NGOs.

In recent years, a number of public-private partnerships (PPPs) have been established to tackle particular health problems. Most target specific products, diseases or technologies. One category of PPPs addresses access to pharmaceuticals critical to treatment or care for diseases disproportionately or uniquely affecting the poor in developing countries. These PPPs for drug access – usually based around provision of products that are donated or heavily discounted and multi-partner efforts at field level to ensure their distribution and proper use – are often the only initiatives addressing diseases that are not high on the political agenda, such as lymphatic filariasis and sleeping sickness.

While these PPPs result in health benefits for the populations that they reach, there are questions about integration, coordination, implementation and impact in relation to health services in the countries where they operate. Key questions include the degree to which involvement of multinational pharmaceutical companies in drug procurement and delivery improves drug availability and access for the poor, the extent to which availability of free or reduced price drugs distorts decisions on priorities or prices, and the feasibility and sustainability of taking such initiatives to scale. These questions are becoming increasingly important as the number of drug access partnerships grows and as countries have to prioritise use of resources in the context of debt relief, sector-wide approaches (SWAps) in health and multisectoral poverty reduction strategies (PRSPs).

The UK Department for International Development (DFID) is funding the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct a series of studies across a range of access partnerships and countries. Following a pilot study in 2003 in Uganda, three studies were undertaken in 2004, in Zambia, Botswana and Sri Lanka. These studies can stand alone but are part of an ongoing IPPPH programme of activities to assess public-private collaboration to improve access to pharmaceuticals for the poor.

Terms of Reference

The key research question concerned the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor. The objectives of the study were:

- To assess the health and health systems impact in Zambia of public-private partnerships for improving access to pharmaceuticals in relation to two tropical diseases – leprosy and malaria – and to HIV/AIDS, examining issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured.
- To assess whether Zambia is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

Key issues for examination included:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, motivation

for involvement and level of support and/or funding.

- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The PPP programme's involvement in, and the effectiveness of, coordinating mechanisms (formal and informal) with other PPPs at all levels, and implications of the programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- The available evidence of impact on (a) coverage and (b) health, including the impact of any inclusion in PPP programme design of specific efforts to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural-urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and management information systems (MIS/HMIS); and government-NGO working relationships.
- The optimal scale of the programme's operations within the country and any plans for taking the programme to scale and for longer-term sustainability.
- The identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

The complete terms of reference can be found at Annex 1.

Method

The study was undertaken in Zambia in March 2004 by a team of three international consultants and one national consultant:

- Qhing Qhing Dlamini (team leader), health development consultant, Swaziland.
- Louisiana Lush, senior lecturer, Health Policy, London School of Hygiene and Tropical Medicine, UK.
- Martin Auton, independent consultant on the management of medicines in public health, South Africa.
- Patrick Nkandu, health consultant, Zambia.

All members of the study team are independent of the IPPPH and the pharmaceutical industry.

This was a rapid assessment rather than a detailed study. Limitations on funding and time precluded original data gathering. Quantitative information was gathered from existing documentation. Qualitative information was gathered from semi-structured interviews with key informants at national and district levels and field visits. The study team:

- Reviewed background documents and literature including global, national and district programme strategies, plans and reports.
- Conducted interviews with key informants at the Ministry of Health and Central Board of Health; Medical Stores Ltd; National Formulary Committee and Pharmacy and Poisons Board; University Teaching Hospital, Lusaka; University of Zambia and Tropical Diseases Research Centre; National HIV/AIDS Council; Churches Health Association of Zambia; WHO; DFID; private medical practitioners and NGOs.
- Visited the four districts of Chibombo, Lusaka, Mpika and Ndola and conducted interviews with district and health facility staff.

A complete list of interviewees can be found in Annex 2.

Criteria for selection of the four districts included: active implementation of PPP; provincial and socio-economic representation; and security and accessibility within the timescale of the study. The study ensured that each PPP was visited in at least one district. The malaria (Coartem®) PPP was reviewed in Chibombo, Lusaka and Mpika districts, the leprosy PPP in Chibombo, Lusaka, Mpika and Ndola districts, and the HIV/AIDS PPPs in Lusaka and Ndola districts.

Acknowledgements

This study could not have been completed without the cooperation of all those who were contacted or interviewed in Zambia. The team wishes to acknowledge the support received from the staff of the Ministry of Health and the Central Board of Health at national, provincial and district levels; the Tropical Diseases Research Centre: the Uni-

Table 1. Districts visited and programmes active in those districts

District	Malaria (Coartem®)	Leprosy	Viramune®	Diflucan®
Chibombo	Yes	Yes		
Lusaka	Yes	Yes	Yes	Yes (at secondary/tertiary level – not managed by district)
Mpika	Yes	Yes		
Ndola		Yes	Yes	Yes (at secondary/ tertiary level – not managed by district)

versity of Zambia School of Medicine; the University Teaching Hospital; the Zambia HIV/AIDS Business Sector Project; Management Sciences for Health; and private medical practitioners.

The team is especially grateful to the Dean of the University of Zambia School of Veterinary Medicine for information on lymphatic filariasis and to the National HIV/AIDS/STD/TB Council, National Malaria Control Programme, Churches Health Association of Zambia, Ministry of Health and Central Board of Health and Ministry of Finance and National Planning for providing other information and background documentation for the study.

The WHO and DFID offices in Lusaka provided valuable assistance and information. Particular thanks are due to the staff of the Zambia Business Coalition on HIV/AIDS for their support to the study team.

Finally, the team would like to thank all the individuals those who provided information, advice and comments during the preparation of this report.

2. Health challenges and the health system in Zambia

The country context

Demographic and socio-economic characteristics

Zambia has a population of 10.2 million. More than half of Zambians (51%) are female and Zambia has a relatively youthful population. Female-headed households dominate, especially in rural areas. Zambia is one of the most urbanised countries in sub-Saharan Africa, with 48% of the population living in towns.

Literacy rates were 76.4% for males and 56.5% for females in 1990 (CSO, 1990). The current estimated national literacy rate is 79%, which is relatively high by African standards. However, school enrolments have declined and literacy, particularly among younger women and girls, has been adversely affected.

In 2001, GDP was estimated at US$ 2.2 billion or US$ 280 per capita (Economic Report, 2001), making Zambia one of the poorest countries in the world. In the Human Development Index (HDI), Zambia is ranked 143rd out of 162 countries (United Nations Development Report, UNDP, 2001). Overall, 80% of the population live in poverty (Ministry of Finance and Planning, PRSP, 2001); 83% of the rural population and 56% of the urban population are classified as poor. Poverty fuels the conditions for the spread of HIV/AIDS and of other infectious diseases including malaria and leprosy. The HIV/AIDS epidemic has also exacerbated existing poverty and created new categories of the poor including child-headed households and street children.

The Zambian economy has limited capacity to raise sufficient resources to address its development and health needs. The proportion of the population employed in the formal sector declined from around 20% to 12% between 1995–1996 and 1999–2000. The economy is weak and dependent on copper exports for foreign exchange. The country has an unsustainable debt burden of about US$ 7.7 billion, and Zambia's call for debt relief is now on the agenda of the Highly Indebted Poor Countries (HIPC) Initiative.

Epidemiological characteristics

Health status has worsened in Zambia during the last two decades. Infant mortality rates have regressed from about 90/1,000 in 1980 to 109/1,000. Maternal mortality is among the highest in the world at 649/100,000 births.

Malaria is endemic throughout the entire country. The predominant parasite is Plasmodium falciparum, the most deadly form of malaria. There are three million clinical cases of malaria causing 50,000 deaths each year, with women and young children especially vulnerable. The disease is a contributing cause of about 20% of pregnancy-related deaths. Malaria also accounts for the greatest number of paediatric outpatient consultations and hospital admissions, and is the most important reason for adult health centre attendance. Malaria has substantially higher prevalence among the poorest population groups. Poor families live in dwellings that offer little protection against mosquitoes and are less able to afford insecticide-treated nets. Poor people are also less likely to be able to pay either for effective malaria treatment or for transportation to a health facility capable of treating the disease.

Records show rising trends in mortality and morbidity, in part due to high levels of resistance to both chloroquine (up to 54%) and sulfadoxine-pyrimethamine (up to 32%). Health centre and hospital admissions attributable to malaria have risen from about 11% of all admissions in 1982, when chloroquine resistance was first reported, to 39% in 1999–2000. Case fatality for patients admitted has also risen dramatically. These data underestimate the burden of disease, given that 50–60% of people seeking health care visit private practitioners.

Leprosy is a chronic infectious disease caused by a bacterium. There are two main kinds of leprosy: paucibacillary (PB), a milder type which usually cannot be transmitted and can be cured with six months of regular monthly multi-drug therapy (MDT); and the more serious multibacillary (MB), which takes 12 months to treat, although the patient is no longer infectious after four to six weeks of treatment.

Leprosy is a longstanding but now comparatively small-scale public health problem in Zambia, following a successful elimination programme. A 2001 WHO report[1] confirmed that 100% MDT coverage of leprosy patients was achieved in 1991, and elimination of leprosy at the national level was reached in 1999 (based on the WHO definition of elimination as less than one patient per 10,000 population). In December 2000, Zambia had 686 registered cases of leprosy (555MB, 131PB), a national prevalence rate of 0.68/10,000. Only two provinces did not reach elimination level: Western province had a prevalence rate of 1.3 and Luapula, 3.3. The proportion of children among reported new cases in 2000 was 4.8%. In 2003, 314 cases were detected. The current prevalence of 247 is far below the WHO elimination target.[2]

The first case of AIDS was reported in Zambia in 1984. HIV prevalence, at around 20% of the adult population, is among the highest in the world. Average Zambian life expectancy at birth is now only 35 years (WHO, 2002). The 2001–2002 Zambia Demographic and Health Survey (ZDHS) found that 18% of women and 13% of men aged 15-49 years were HIV-positive. Even more worrying, almost 50% of women in this age group living in urban areas were infected. An estimated 8% of young men and 17% of young women aged 15-24 years are HIV-positive. By 2002, prevalence at selected antenatal sentinel surveillance sites had reached 26% in urban areas and 11% in rural areas, and 30–40,000 infants are infected through mother-to-child transmission each year. As of June 2000, 830,000 adults were living with HIV/AIDS, of whom 450,000 were women (Report of the 13th Consultative Group Meeting, 2002). The HIV/AIDS epidemic has orphaned 620,000 children – the number is projected to rise to 974,000 by 2014 (MOH, 1999).

Factors that contribute to the spread of HIV in Zambia include the high prevalence of sexually transmitted infections (STIs), multiple sexual relationships, low condom use, early sexual debut, harmful cultural practices, poverty, gender inequalities, urbanisation and population mobility (HIV/AIDS in Zambia, 1999).

The health system in Zambia

In Zambia, health care is provided by government and mission facilities, private practitioners, private sector companies and traditional health providers. The health system is predominantly public. While there has been an increase in private sector provision of health care, this remains relatively limited and concentrated in urban areas. There are 1,199 health institutions located in Zambia's nine provinces and 72 districts. These include three central hospitals, nine general hospitals, 36 district hospitals, three specialist hospitals, 30 mission hospitals, 12 industrial hospitals, five unclassified government hospitals, 808 rural health centres and 206 urban health centres. The 30 mission hospitals and 61 health centres are run by different churches and their activities are coordinated by the Churches Health Association of Zambia (CHAZ). These facilities are an integral part of the government health system, and the Ministry of Health (MOH) supplements their running costs. Private sector companies, particularly, the mines, have their own health care system providing services to employees and their families at the 12 industrial hospitals and 72 health centres.

To ensure that the health system is responsive to priority health needs and improve the health status of the Zambian population, the MOH has undertaken a series of strategic reforms. Key components of these reforms include the adoption of a Basic Health Care Package (BHCP) and an integrated system for management and delivery of clinical, environmental and public health services to maximise use of available resources.

In 1982, the Zambian government launched a pilot study to determine how the Alma Ata principles of primary health care could be adapted to Zambian conditions. This resulted in a first phase of health reforms, which were intended to shift the emphasis from curative care to prevention and health promotion and to respond to serious but

[1] Dr A. O. Awe WHO/STC in collaboration with the National TB/Leprosy Control programme, Central Board of Health, *Report of Technical support for the Implementation of Leprosy Elimination Campaign and Review of Leprosy Elimination Data in the Republic of Zambia, 21 July to 8 August 2001*

[2] Dr D. Daumerie, WHO Geneva, personal communication.

preventable health problems such as malaria, diarrhoea, acute respiratory infections, measles, meningitis, cholera and TB. Between 1985 and 1990, a second phase of reforms was implemented. Recognition of the need to update the legal framework for health services led to the Health Services Act of 1985. This included the concepts of decentralisation, autonomy and user fees.

Analysis of the first two phases of the health reform process identified a number of deficiencies and, in 1992, a new national health policy document was produced that aimed to address these by decentralising decision-making to the district level and implementing a new management structure that allows for private sector and NGO participation in service delivery (MOH, 1992). This policy document outlined the objectives of health reform process that is currently underway in Zambia.

As a result of the reforms, the MOH at national level is responsible for resource mobilisation, policy formulation and strategic planning. The Central Board of Health (CBOH) is responsible for provision of health services (which is fulfilled largely through contracting district health and hospital boards), interpreting and implementing health policies, and monitoring the performance of health boards. With regard to medicines, the CBOH is also responsible for developing guidelines including treatment protocols and ensuring a reliable supply of drugs and related commodities through a process of national selection, quantification, procurement and distribution.

Notable achievements include development of a system for equitable distribution of funds to districts, and improved accountability. More equitable distribution of resources to districts has equalised opportunities for health sector development throughout the country. The decentralised system is largely transparent, with efficient accounting procedures in place. Decentralised services have also provided scope for flexibility and innovation in health services.

Funding for the health system

Increased government commitment to health has resulted in an increase in budget allocations to the MOH from 8% of government spending in the 1980s to the current level of 14%. However, the poor economic climate continues to have an adverse impact on financing available for the health sector.

Resource constraints have been a longstanding constraint to achieving the government's objectives of equity and accessibility in the use, consumption and distribution of health services. As a result, in the early 1990s, the government introduced cost sharing into public health services. Recognising that poor households faced severe difficulties in paying user fees, the government also introduced the BHCP of interventions – based on the main causes of mortality and morbidity in terms of disability adjusted life years (DALYs) – to be provided at tertiary, secondary and primary levels of the health system.

However, there is a gap between the cost of providing the BHCP – estimated at US$ 15 per capita per year – and the public health budget – US$ 10 per capita per year. Of the US$ 10 per capita available last year, 60% was spent on district health services. The deficit for delivery of the BHCP is therefore US$ 9 per capita, which translates into a national resource deficit of US$ 90 million, based on the population of 10.2 million.

Steps taken by the Zambian government to harmonise the public financing system and funding for health services include:

- Contracting for services through fund-holding boards to ensure accountability, transparency and the existence of a performance based delivery system.
- Decentralised planning and decision-making, and the development of a private-public mix to expand primary health care services.
- Unification of financial and non-financial resource support from donors and the government, with the National Health Strategic Plan, annual action plans and budgets providing the basis for programme and financial accountability and performance. The unified approach is also intended to support programme harmonisation through integrated management, planning, monitoring and evaluation.

The impact of HIV/AIDS on the health sector is both direct and indirect. The direct impact includes increased costs associated with treating opportunistic infections (OIs) and caring for those dying from AIDS. HIV-related health care costs are estimated to have increased from US$ 3.4 million in 1989 to US$ 18.3 million in the late 1990s (GFATM Round 1 Proposal). The burden on hospitals is especially high with around 70% of beds reportedly occupied by patients with AIDS-related

conditions. The indirect impact includes attrition of health sector personnel through HIV/AIDS-related illness and death.

As of December 2003, the National HIV/AIDS/STD/TB Council (NAC) estimated that of the US$ 560 million Zambia required for prevention, treatment and care interventions for the period 2002-2005, the government had allocated US$ 95 million, while US$ 24 million has been contributed from the World Bank Multisectoral AIDS Programme (MAP) and US$ 60 million from GFATM. Despite these contributions and commitments from other donors, there was still a shortfall of US$ 170 million.

Drugs policy, procurement and management

Medicines policy in Zambia

The National Drug Policy (NDP) 1999 states that: "The government is committed to the provision of equity of access for all Zambians to good quality, safe and efficacious medicines which are affordable and rationally used as close to the family as possible". The main aims of the NDP are:

- All medicines and information conform to standards for quality, efficacy and safety from manufacture to the patient, and pharmaceutical practices are carried out by appropriately trained personnel.
- A total quality assurance system for medicines and related products.
- Sufficient funding is made available to provide adequate quantities of good quality essential medicines.
- Procurement of good quality medicines and raw materials at the lowest price.
- Prompt, safe and efficient distribution from the central level to facilities so that quality is maintained and drugs are available and accessible to all in need at all times.
- Create an enabling environment in which local pharmaceutical manufacturing will be able to grow and contribute to the overall aims and objectives of the NDP.
- Rational use of medicines, provision of adequate information and eradication of unnecessary and inappropriate medicine use at all levels of society.
- Develop a medicines list for each level of health care and provide policy direction for selection of medicines at different levels by district Pharmacy and Therapeutic Committees.
- Develop an efficient and effective pharmaceutical service in the public and private sectors to support the successful implementation of the NDP.
- Strengthen research and development capacity and competence to support the NDP's objectives.
- Research medicinal materials in home and traditional remedies in terms of identification of active ingredients and safety, and establish a traditional medicines practitioners' council to regulate the activities of traditional healers.

Table 2. Key indicators

Date of National Drug Policy	1999
Date of Essential Drugs List	1999
Date of National Formularies	1991; 1999
Date of National Standard Treatment Guidelines	1999
Public sector per capita medicines budget (2000)	U$ 1.1[1] (≈ 10% health budget)
Public sector per capita medicines budget (2003)	U$3.50[1]
Estimated public sector per capita medicines expenditure (government and cooperating partners)	U$1.00[2]
% products on Zambian market registered (estimate)	30%[3]

The 2001–2005 National Health Strategic Plan identified effective implementation of the 1999 NDP as a key priority. This is to be achieved through: ensuring adequate resources for medicines and supplies, together with improvements in procurement and distribution systems; reviewing and updating the essential drugs list (EDL) and guidelines; enacting the Pharmacy Law and building pharmaceutical human resource capacity. The NDP

[1] National Health Strategic Plan 2001–2005, Ministry of Health, December 2000.

[2] Estimate for 2000; Mid Term Review Report: National Health Strategic Plan 2001–2005, Ministry of Health, February 2004.

[3] Situation analysis, 1996, National Drug Policy, Ministry of Health, 1999.

Steering Committee, established in 2001 to direct and monitor the implementation of the policy, is currently developing an Implementation Plan and Monitoring and Evaluation Tool. Zambia developed its first EDL in 1999. In the view of the National Health Strategic Plan 2004 view, the Essential Drug Committee did not meet often enough and was "only consulted to approve decisions already made by MOH and CBOH, particularly on anti-malarial treatment".

Some districts and facilities have established Pharmacy and Therapeutic Committees to advise on selection and management of medicines. MOH policy is that interventions not included in the BHCP should be recovered at full cost. However, the selection of medicines for the public sector is currently wider than is required to implement the BHCP; other interventions can be offered if patients provide the necessary medicines. The Pharmaceutical Society of Zambia (PSZ) is contracted annually to promote rational drug use to the public and health workers.

Legislation and regulation

Zambia has five acts dealing with the control of medicines, pharmacy and poisons. These are old and do not reflect the current situation or practices. For example, the Pharmacy and Poisons Act dates from 1941. At present, assuring safety, quality and efficacy of medicines in the public and private sectors is the responsibility of the Pharmacy and Poisons Board, the medicines regulatory authority in Zambia.

New legislation designed to support implementation of the NDP was developed in 2000, and formal drafting commenced October 2003. The new Act would establish a Pharmaceutical Regulatory Authority, which would replace the Pharmacy and Poisons Board and would have increased powers to regulate the quality, safety and efficacy of medicines through control of manufacture, import, export, distribution, promotion and clinical trials. Zambia is also participating in the lengthy and complex process of harmonisation of medicines regulatory issues within the Southern Africa Development Community (SADC).

Supply, procurement, storage and distribution

The district and hospital management boards are responsible for ensuring that essential medicines are available in public health facilities. At national level, responsibility for ensuring that medicines are available to the districts and hospitals is split between MOH, CBOH and Medical Stores Limited (MSL). MSL is a limited parastatal company responsible for receiving and storing medicines procured by CBOH and for distributing medicines under instruction from CBOH and district and hospital boards. Management of MSL was contracted out in 1998. The contract recently expired and, pending the re-tendering process, an interim MOH management team is in place at MSL. CHAZ manages a medicines store on behalf of its mission health facility members, procuring and selling medicines to its members and processing importation procedures for medicine donations.

Manufacturing capacity in Zambia is limited. However, a new manufacturing company based in the former manufacturing unit at MSL has just received permission from the Pharmacy and Poisons Board to produce ARVs.

The Procurement Unit of CBOH is responsible for procurement of medicines, mainly through international tendering. In addition, districts may use 4% of their budget to purchase medicines. The Procurement Unit is understaffed and underequipped, especially in view of the tripling of the public sector medicine budget between 2000 and 2003 (largely due to the procurement of more expensive medicines for malaria and HIV/AIDS) and responsibility for managing the Diflucan® and Viramune® PPPs. Zambia has participated in discussions with the Commonwealth Secretariat and SADC concerning pooled procurement.

Since the mid-1990s, major efforts have been made to integrate stock and distribution systems for the large number of vertical programmes and, with the exception of vaccines, all programmes have been integrated into MSL. Over 25 health programmes involve medicines managed by MSL, with some products being part of a number of different programmes. Most of these programmes require separate reconciliation and some also have their own specific reporting requirements and separate reporting systems. Although MSL charges 5% of the value of medicines received and 10% distribution fees to cover the costs of receipt, storage and distribution, it is reported that these charges do not cover all of the costs for programmes that require parallel recording and reporting systems.

MSL distributes drugs to district and hospital boards on a monthly schedule drawn up 12 months

in advance. While this is a significant improvement on the situation in the mid to late 1990s, some boards have reported that the schedule is not always maintained.

Human resources

There are many private retail and wholesale pharmacies in Zambia, mainly located in urban areas, which employ the majority of trained pharmacists. The country lacks adequate numbers of trained pharmacists and pharmacy technologists to manage the public sector medicines system. In most districts, lower level hospitals and virtually all health centres operate without any pharmaceutically trained staff. However, 2,400 health workers have been trained on medicines stores procedures and quantification of medicines and medical supplies. A District Integrated Logistics Self Assessment Tool has been developed to assist districts in management and use of medicines and supplies.

3. Drug access PPPs in Zambia for tropical diseases: Malaria (Coartem®) and Leprosy

Background information on the Leprosy and Malaria (Coartem®) PPPs in Zambia

Zambia participates in PPPs for improving access to pharmaceuticals in relation to two tropical diseases: malaria and leprosy (see Table 3). In each case, the drug access PPP is currently operating in liaison with two wider disease-focused global partnerships – the Roll Back Malaria Partnership and the Global Alliance to Eliminate Leprosy (GAEL) – and the WHO Roll Back Malaria and leprosy elimination programmes.

Malaria

WHO currently recommends artemisinin-based combination therapy (ACT) for treatment of malaria where resistance levels to first line drugs are over 15%. Coartem®, the first co-formulated artemisinin-based combination therapy, was developed by Novartis with Chinese partners and registered in 1998. At the international level, Novartis approached WHO to discuss product distribution through a PPP, which involves a dual branding, triple pricing approach, whereby WHO is able to purchase the product at a non-for-profit price, while Novartis sells a commercial pack in the private sector. In 2001, Novartis and WHO signed a 10-year agreement. Coartem® (artemether-lumefantrine), a patented single source product, is the only fixed dose combination available. All other ACTs are so far only available as co-administered individual products, sometimes in special co-packaged blister packs.

The product is distributed in four presentations, each containing an appropriate unit dose based on body weight. Novartis and WHO have developed educational materials to support effective treatment and adherence. In 2003, around 2.7 million treatments were shipped to the public sector in endemic countries. The product is registered in over 70 countries, although as yet it is the recommended first-line treatment in only a few countries in sub-Saharan Africa. Efforts are continuing to investigate the safety profile for pregnant women and infants. Currently only WHO may receive public sector Coartem® from Novartis, and a WHO Technical Advisory Group reviews country requests either direct from countries or through NGOs.

Table 3. Global Malaria and Leprosy PPP programmes

	Malaria (Coartem®)	Leprosy
Global PPP programme and objective	*Roll Back Malaria (RBM)* Reduction of malaria mortality and morbidity.	*Global Alliance for the Elimination of Leprosy (GAEL).* Elimination by 2005 To "ensure that all patients, wherever they may be, will have free and equal access to the most modern treatment available".
Donation/preferential price	Novartis' agreement to sell Coartem® at cost to WHO for malaria treatment for 10 years from 2001–2011.	Novartis' global commitment to supply free MDT for all endemic countries until the end of 2005 is to be extended until 2010.
Conditionalities	Nothing unreasonable. WHO Geneva conducts quarterly rolling forecasts and an annual three-year forecast for Novartis. Novartis requirement that drug costs for patients are reasonable. Programme conditionalities imply that repeated product diversion to unauthorised private providers could result in product withdrawal, although it is too early to assess how diversion incidents will be dealt with in practice.	Nothing unreasonable.

Zambia has received Coartem®, procured under the Novartis-WHO PPP agreement, through three channels since February 2003. The first consignment was a donation of 800,000 tablets from Médecins sans Frontières[1] (MSF) in February 2003, facilitated by WHO and the Zambia National Malaria Control Programme (NMCP). This consignment, originally intended for Burundi, was rerouted to Zambia after treatment guideline changes in MSF and, when the drug reached Zambia, the expiry date was about three to four months away. The MSF donation made it possible to implement the new Zambian policy on Coartem® as a first-line treatment (see Country priorities below) from April 2003 in seven pilot districts, where the NMCP undertook rapid training and distribution of materials. While the drug was well accepted by providers and patients, stocks were only sufficient to last during April and May 2003. The second consignment of Coartem®, to the value of US$ 60,000, came directly from WHO in August 2003. In September 2003, this was made available in the same seven pilot districts, to address stock outs after the MSF donation ran out.

The third consignment of Coartem® was negotiated through the GFATM. (When Zambia's Round 1 proposal was approved, GFATM issued a letter of credit to Novartis, since Zambia had not yet satisfactorily completed its procurement and supply management assessment.) Since December 2003, Novartis has made available 1.5 million courses of Coartem® to 28 pilot districts, out of a total commitment of 2 million and a total cost of US$ 3.3 million. During 2004, year 2 of the GFATM proposal, a further US$ 5 million will facilitate expansion. The government target is to cover the whole country by 2006. As set out in the GFATM proposal, the objective is to accelerate going to scale, aiming to cover all districts by the end of 2004, although this could pose logistical challenges, particularly in terms of ensuring staff training rollout.

Leprosy

Since 1999, Novartis has donated free multi-drug therapy (MDT) for leprosy for all endemic countries under an agreement with WHO through a programme managed on their behalf by the Novartis Foundation for Sustainable Development (NFSD). The current agreement is due to end in 2005, the WHO target date for elimination, but Novartis and NSFD are to extend its donation until 2010. Novartis does not make MDT commercially available and supplies WHO with sufficient stock for all patients in the world. WHO continues to provide limited support for training and special campaigns targeting areas where leprosy has not been eliminated. Before receiving MDT under the WHO-Novartis programme in 1999, from 1997–1999, MDT was provided by WHO using the drug fund financed by the Nippon Foundation.

Multi-drug therapy (MDT) was introduced in a few pilot districts in Zambia in 1986, when leprosy control activities were initiated in the country, and national MDT coverage was achieved in 1991.[2] MDT has an important side benefit allowing patients to be treated in their own home areas, so that leprosy facilities (31 in 1968) closed down or converted to general hospitals. This is also important in reducing isolation and stigma. There was disruption of the national programme in 1997–1999 as a result of the health reform policy, as reported in WHO's 2001 evaluation, and some problems with data collection and collation. Despite this, elimination of leprosy at the national level was reached in 1999 (based on the WHO definition of elimination as less than one patient per 10,000 population).

Key findings

Table 4 summarises the programme objectives and performance of the PPPs for malaria (Coartem®) and leprosy. More detail on national malaria policy and programmes is provided in Annexes 3 and 4.

Country priorities

Malaria (Coartem®)

The malaria (Coartem®) programme is a high priority in Zambia. With support from WHO Roll Back Malaria (RBM), the MOH and CBOH made a policy change in November 2001 and moved from chloroquine (CQ) as a first-line drug for treating uncomplicated malaria to the combination therapy artemether-lumefantrine (Coartem®). This policy change was a response to the magnitude of the malaria burden and the high resistance to chlo-

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[1] MSF were already using ACT treatment in their refugee camps in North West Zambia on the Congo border.

[2] Dr A. O. Awe WHO/STC in collaboration with the National TB/Leprosy Control programme, Central Board of Health, *Report of Technical support for the Implementation of Leprosy Elimination Campaign and Review of Leprosy Elimination Data in the Republic of Zambia, 21 July to 8 August 2001.*

Table 4. National Leprosy and Malaria programmes

	Leprosy	Malaria (Coartem®)
National programme objective	To reduce the prevalence of leprosy in the country. To reach the elimination target (<1 patient per 10,000 inhabitants) at sub- national level in endemic areas.	To reduce malaria mortality and morbidity by increasing access to effective malaria treatment in the light of chloroquine (CQ) resistance and other measures.
National programme initiated	Leprosy control activities initiated and MDT introduced 1986. MDT 100% coverage achieved from 1991. Programme integrated into TB/HIV/ STD in 1991. Zambia joined the WHO-Novartis programme in 1999. From 1997–1999 MDT was provided by WHO using the drug fund financed by the Nippon Foundation.	Longstanding National Malaria Control Programme. RBM strategic framework adopted in 2000, followed by development of a medium term Strategic Plan for 2001–2005.
Population at risk	Information not available.	Endemic throughout the country. Those most vulnerable to malaria include children <5 years, pregnant women and population in rural areas.
National partners	MOH, CBOH, Provincial Health Management Teams (PHMTs), District Health Management Teams (DHMTs), CHAZ, TLMI, NLRI, WHO.	NMCC, PHMTs, DHMTs, NGOs, TDRC, WHO, UNICEF, JICA.
Current national/ provincial government contribution	Unquantified. Includes salaries for CBOH TB/ leprosy staff, CBOH Pharmacy and MSL staff, PHMT and DHMT leprosy focal points, service delivery staff and drug supply staff.	Unquantified. Includes salaries for the NMCP staff, CBOH Pharmacy and MSL staff, PHMT and DHMT malaria focal points, service delivery staff and drug supply staff.
Current national coverage	Total national coverage of MDT achieved in 1991 and maintained to-date. Some problems with supply reported by CHAZ in 2002.	28 pilot districts of the 72 districts in the country by March 2004.
Performance against targets	Elimination at the national level was achieved in 1999, with a 2000 national prevalence rate of 0.68 against a WHO elimination target of <1 per 10,000 inhabitants. However, in Western and Luapula provinces, prevalence rates were 1.3 and 3.3 respectively.	Coartem® is targeted at public sector patients in all 28 pilot districts as per strategic plan. NMCP plans to scale up to all 72 districts by the end of 2004
Reporting system for drug	Health centres send monthly reports to DHMT. District sends monthly consumption forms to TB/leprosy Specialist at CBOH. Drug requisitions from districts processed quarterly by Pharmacy Department. Drug orders distributed quarterly from MSL to district with drug kits. Drugs distributed to health centres quarterly with drug kit.	Health centres send monthly returns to the district office where information is collated and sent to the NMCP. Monthly forecasts made by the NMCP to WHO. Initially a "push" system, based on CQ/SP consumption and malaria incidence, was used for drug allocation. Subsequent drug allocation uses a "pull" system, based on Coartem® utilisation/ consumption. Also a new pharmacovigilance system is being developed on especially for inadvertent use in pregnant women and children under 10 kg, when reporting is mandatory
Sustainability	The close working relationship between the national MOH and CBOH leprosy control programme and CHAZ leprosy control programme with the support of TLMI will ensure sustainability. Netherlands Leprosy Relief International has recently signed an agreement with CBOH to fund CHAZ' leprosy programme.	The MOH and CBOH made a radical policy change from CQ to Coartem® in November 2001. Its new partners are Novartis and the GFATM, with funding secured for three to five years. In future, the MOH and CBOH will need to budget for Coartem®.

roquine identified in resistance studies conducted in Zambia. Resistance had tripled in the past 20 years and now ranges from 10–54% across the country.

During 2002, in consultation with WHO, the MOH revised their malaria treatment guidelines, selected the drug to be used and made plans to phase out the use of chloroquine in the public sector. CQ was withdrawn from all health facilities and sulphadoxine-pyrimethamine (SP) was used in the interim as a first-line drug for treating uncomplicated malaria. Some resistance to SP has also been found in some sites.

The MOH and CBOH went ahead with the policy change despite reported resistance from Zambia's traditional development partners. At the time, the government was aware of the "preferential price" for Coartem® through its interaction with WHO Geneva Roll Back Malaria Partnership. Annex 4 shows a timeline for malaria and Coartem® policy globally as well as in Zambia, indicating the various interventions from players including the government, WHO, Novartis, GFATM and MSF.

Consistent with the new national policy, the NMCP has quantified the amount of Coartem® required to enable all Zambians to access this new drug. However, the cost of Coartem® initially prohibited accelerated expansion to all districts. As of March 2004, additional funds made available through the GFATM, WHO and other sources had enabled the government to increase quantities to provide coverage to 28 districts. The government is mobilising additional resources through the GFATM to cover all 72 districts in the country by end 2004.

Leprosy

Zambia has a long-established leprosy campaign, and the disease is in the final stages of elimination as part of a global initiative to eliminate leprosy by end 2005. The integrated National TB and Leprosy Programme is jointly coordinated by the CBOH and CHAZ. The CHAZ Leprosy Focal Point plans jointly with the TB and Leprosy Control Programme and spends two days a week in the CBOH.

Thirteen of CHAZ's mission institutions in seven provinces are receiving additional support from The Leprosy Mission International (TLMI) through a five-year project, which runs until 2005. Netherlands Leprosy Relief International (NLRI) has recently signed an agreement with the CBOH to fund the CHAZ Leprosy Control Programme.

Patient follow-up and management is integrated with the TB programme. Leprosy control at district level is regarded as an important, though no longer significant, activity, in terms of time and allocation of resources. Anecdotal reports in the four districts visited by the team indicated that few cases of leprosy are seen. Ndola Central Hospital, for example, reported that they had not seen any cases of leprosy for some time, and therefore did not have any drugs in stock. Lusaka DHMT reported that in 2003 they had five new cases and had a total of 20 patients on the register. Chilonga Mission Hospital in Mpika district had two to three new cases a year, and Kapa clinic the same district had eight patients on treatment. There was no evidence to suggest that the Novartis donation distorts government priorities or the allocation of human or financial resources.

Ownership and governance

Governance of, and decision making within, the PPP-assisted national programmes was found to rest at national level, accepting the need to comply with criteria for involvement in the two global health partnerships. The study found no evidence of unreasonable conditionalities specified for the tropical disease drug access PPPs, for example in relation to scope of programme, drug indications or modes of operation.

Malaria (Coartem®)

Zambia has successfully developed a national strategic institutional framework for combating malaria, involving the public, private and NGO sectors, and inter-country and regional consultation processes. The country is already implementing some of the planned Roll Back Malaria and Strategic Plan activities and the GFATM supports these efforts. The National Malaria Control Centre (NMCC) is one of the secretariats to the GFATM Country Coordinating Mechanism (CCM), which plays a key role in coordinating the malaria programme. The MOH and CBOH national malaria specialist is the acting director of the NMCC, coordinates all activities related to malaria in the country, including the Coartem® programme, and reports to the Director of Public Health and Research in the CBOH who in turn reports to the Director-General of the CBOH.

Leprosy

As noted earlier, the integrated National TB and Leprosy Programme is jointly coordinated by the CBOH and CHAZ. The TB and leprosy specialist, based at the CBOH, reports to the Director of Public Health and Research. (The leprosy specialist post is currently unfilled and the Leprosy Focal Point at CHAZ was fulfilling the role at the time of the study.) The CHAZ Leprosy Focal Point plans jointly with the TB and Leprosy Control Programme and spends two days a week in the CBOH. The CHAZ Leprosy Focal Point reports to the CHAZ Director of Programmes. Governance of CHAZ is through an Annual Council.

Integration with general health services

Malaria (Coartem®)

At national level, the programme is run as a separate specialist unit, which coordinates policy and implementation. It is important to note that many African countries, including Zambia, have separate programmes, but that this is not a consequence of the Novartis discount programme, which, other than drug procurement, is now fully integrated with national systems.

Currently, WHO Geneva procures Coartem® for Zambia after funds equal to the total costs (estimated by WHO) are deposited in US dollars to the credit of WHO (see Table 5). Novartis charges WHO the subsidised price of US$ 2.40 per adult treatment course. WHO charges the government a management fee of 3% of the unit cost of the consignment. Upon completion of the transaction, WHO sends the government a statement of account with supporting documentation. The consignment is cleared by the WHO country office, which transfers the stock to MSL. MSL keeps an inventory of Coartem® and distributes the drug according to instructions received from NMCP. MSL charges a management fee for storage and distribution (5% and 10% of the unit cost for management service and distribution to district level). At district and health facility levels, drug distribution is fully integrated into general health services and the programme is part of the routine Health Management Information System (HMIS).

Of the four districts visited by the Zambia study team, three were Coartem® pilot districts. In two of the districts, the team visited a district hospital – Liteta hospital in Chibombo district and Mpika hospital in Mpika district. The team also visited Chilonga mission hospital in Mpika district. In Chibombo district, Coartem® for the whole district is ordered and stocked by the district pharmacist, who is based at Liteta district hospital. The district has been using Coartem® since early 2003. In Mpika district, the pharmacy technologist at Mpika district hospital orders and stocks Coartem® for the district, where the drug has been used since February 2004.

Table 5. Current cycle of drug ordering, receipt and distribution

	Leprosy	Malaria (Coartem®)
Application process and orders for drugs	By CBOH TB/leprosy specialist through WHO Representative to WHO Geneva.	By CBOH malaria specialist through WHO Representative to WHO Geneva.
Estimation of drug requirements	By TB/leprosy specialist with input from DHMTs, based on utilisation/ consumption at health facility level.	By malaria specialist with input from DHMTs, based on utilisation/ consumption at health facility level.
Receipt of drug in country	WHO	WHO
Storage	Medical Stores Ltd (MSL)	Medical Stores Ltd (MSL)
Distribution to district level	MSL delivers quarterly to DHMT with district drug kit. DHMT in turn distributes quarterly to health facilities along with facility drug kit.	MSL delivers monthly to DHMT with district drug kit. DHMT in turn distributes monthly to health facilities along with facility drug kit.
Distribution to individuals	Patient collects monthly supply from supervising health facility.	Patient given public sector regime, according to age/weight when presents to health facility with signs and symptoms of malaria.
Links with other programmes	Integrated TB/leprosy programme, which appears vertical at national level. At district and facility level, integrated into general health services.	None. Appears vertical at national level. At district and facility level, integrated into general health services.

There were some early problems reported with supply of Coartem® to secondary and mission hospitals, although these did not appear to be linked to the discount programme itself. Initially, the national programme introduced drug ordering and distribution mechanisms that were not in line with normal supply arrangements to secondary and mission facilities, which meant that some facilities did not receive supplies. Problems with the design of the system were soon identified. Efforts have now been made to integrate Coartem® into the mainstream drug management system, and supply problems faced by some hospitals are being addressed.

The Coartem® initiative is currently restricted to the public sector, as per the PPP agreement. However, around half of malaria patients seek treatment in the private sector, and the CBOH has agreed with WHO-Novartis to explore private sector provision, through authorised providers. It is developing a pilot social marketing programme, with a non-governmental organisation established by the Pharmaceutical Society of Zambia and Population Services International, which will make Coartem® available through selected retail pharmacies or shops in districts where the drug is distributed in the public sector.

The government will use GFATM funds to finance the procurement of Coartem® from Novartis through WHO. The cost of storage, distribution and contracting will be covered by the sale price of the product to private sector retail outlets. The proposal has been agreed in principle between the government, WHO and Novartis. It is envisaged that this programme will begin in three districts in October 2004 and will scale up gradually over two years. The contract, for storage and distribution of Coartem®, will be guided by the NMCC in line with existing government policies and legislation. Coartem® will be sold at an agreed price between the contractor and the outlet, including a small dispensing fee.

Leprosy

At national level, the drug donation programme is integrated into existing drug supply arrangements. It uses an adapted MOH and CBOH drug ordering system, under which requests for Novartis' donated MDT pass through the CBOH and CHAZ and the drugs are distributed through the mainstream drug distribution system.

Health and health systems impact

Malaria (Coartem®)

The Coartem® discount programme specifies certain conditionalities, including that countries have to formally request Coartem® from WHO Geneva, and register and include the drug in national treatment guidelines. A distribution system must be in place, and use of drugs procured must be accounted for. The product can be distributed by authorized private providers, so long as the price is not 'unduly raised'.

Given the high price of the drug, and growing demand for it, there is clearly a risk of diversion of Coartem®, and stocks in public facilities and at private pharmacies will need to be monitored. Programme conditionalities imply that repeated product diversion to unauthorised private providers could result in product withdrawal, although it is too early to assess how any diversion incidents will be addressed in practice.

Although there is as yet no evidence to demonstrate health benefits, discussions with staff at national and district levels indicate that the Coartem® initiative has benefited the population, since patients who present with uncomplicated malaria no longer face the problem of not responding to treatment as a result of resistance to the first-line drug. Demand is increasing at community level, with anecdotal reports of increasing numbers seeking treatment from public facilities.

Initially, the Coartem® distribution mechanism did not use normal drug supply channels, and lack of consultation was reported between programme and drug supply staff. Although not linked directly to the discount programme's conditionalities, this did not contribute to a smooth introduction of Coartem® into the health system. Given that Coartem® is a new therapy, and demand is increasing, there appear to be some initial problems with forecasting, requisition and supply at the facility level. Initially a "push" system, based on historical drug consumption and malaria incidence, was used for drug allocation. Facilities are moving to a more challenging "pull" system, which is based on reports of Coartem® utilization and consumption, and is more appropriate, given the cost of the drug and the need to monitor and prevent diversion.

Interviews also suggest that the PPP is helping to build the capacity of the health system in a number of ways. One example is the addition of a pharmacovigilance programme, especially for moni

toring inadvertent use in pregnant women and children under 10 kg, for which a report is mandatory, which will eventually be expanded to ART. It is too early to assess the effectiveness of the system, given difficulties experienced in other countries with systems for reporting adverse reactions. Another is that recognition of the high cost of Coartem® has motivated the MOH and CBOH to take steps to strengthen prevention and diagnostic aspects of malaria control.

Novartis also plans to provide support to Zambia's malaria capacity building programme, in relation to training, communications and research, at an estimated cost of US$ 2.2 million over three years.

The main thrust of the support will be training 300 frontline health workers – nurses, clinical officers and environmental health technicians – from health centre level all over the country. The training, scheduled to begin in September 2004, will focus on malaria case management, diagnosis, treatment and choice of drugs, including workshops to train people in communicating dosing instructions to enhance patient compliance and treatment outcomes. Participants will be expected to share information gained in the workshops with colleagues in their workplaces, preferably through formalised cascade training sessions.

In parallel, Novartis has provided Zambia with education materials (posters, leaflets and brochures) in English and major Zambian languages to help health care professionals better instruct patients and caregivers on Coartem® treatment. For the general public, the company is making a financial contribution to enable the NMCC to carry out information, education and communication activities using radio, television and the press among other approaches.

Novartis is also assisting the NMCC in improving its practices on the basis of its experience with Coartem®. Since Zambia is one of the first countries to handle the Coartem® in bulk, it is serving as a model to share best practices and lesson learning with other countries intending to implement ACTs as first-line treatment. Consultancy support is being provided to improve current practices in stock management and drug forecasting.

Operations research will be conducted involving such areas as ascertaining the efficiency of the drugs and health seeking behaviour of the public. A pregnancy register study will be conducted, with the primary objective of evaluating the safety of Coartem® and sulphadoxine-pyrimethamine in pregnant women with symptomatic malaria. Their infants will be followed up to 12 months.

Leprosy

Based on the WHO definition, leprosy has been eliminated at national level, and 100% coverage with MDT had been achieved, prior to the initiation of the WHO-Novartis agreement in 1999. However, there remain pockets of higher prevalence. In 2000, two Western and Luapula provinces have still not reached elimination level, reported to be due in part to refugee migration from neighbouring countries.

Scale and sustainability

Malaria (Coartem®)

Coartem® is an effective drug for the treatment of malaria where resistance is a major concern, and would be difficult for Zambia to access financially in the absence of steep price discounts and GFATM grants.

National commitment to providing Coartem® for malaria is felt to be high. There were a few reports of concerns among some bilateral agencies about the sustainability of the programme, because of the relatively high cost of the drug. Novartis' discounted price under the PPP is US$ 2.40 per adult treatment, compared with a private sector price in Zambia of US$ 12. However, even the discounted price is still relatively expensive compared with the superseded (because no longer effective) policy of chloroquine treatment, which was very cheap at US$ 0.20 per treatment.

Currently, support is provided by Novartis and the GFATM but there are time limits on this, and questions have been raised about the ability of the government to continue to finance provision of Coartem®. Grants from the GFATM are likely to sustain procurements for at least the next three to five years. Future sustainability will require the government to include Coartem® in the national health budget.

Leprosy

Given Zambia's success in eliminating leprosy in most provinces, the leprosy programme is relatively small scale. Close collaboration between the CBOH and CHAZ, together with support from TLMI and

NLRI, should ensure the sustainability of the programme.

Some CHAZ facilities had reported stock outs of MDT in 2002. This was a concern since CHAZ provides health services to 30% of the overall population and to 50% of the rural population in Zambia. However, the problems appear to have been related to internal organisation and logistics, rather than to the drug access PPP, and steps have been taken to address them. All four districts visited by the team had adequate stocks of MDT for their small numbers of patients.

Perceived benefits

Malaria (Coartem®)

Health professionals perceive several health system benefits from the introduction of the new drug, including a new consciousness of the need to strengthen the prevention and diagnostic aspects of malaria control because of the high cost of the drug, and new health system elements such as pharmacovigilance, which will eventually be extended to anti-retroviral therapy for HIV/AIDS. As described above, Novartis is also providing capacity building inputs to support the introduction and use of the drug, and to develop best practice for sharing with other countries.

There is little doubt that Zambia would find it difficult to finance provision of Coartem®, an effective but expensive drug for the treatment of malaria where resistance is a major concern, in the absence of significant price discounts and GFATM funding. Both the Novartis programme and earmarked financing have enabled Zambia to adopt, and begin to implement, the new policy. As mentioned earlier, national and district level informants indicated that the PPP has benefited patients with malaria that is resistant to CQ.

Leprosy

While the supply of donated MDT through the PPP remains an important contribution, 100% coverage with MDT had been achieved, and leprosy eliminated at national level, prior to the initiation of the WHO-Novartis agreement in 1999. From 1997-1999, MDT was provided by WHO using the drug fund financed by the Nippon Foundation.

Outstanding challenges

Malaria (Coartem®)

Key challenges will be ensuring that the supply of Coartem® is not interrupted at either procurement or distribution stages because of financial or logistical reasons, especially once the programme scales up from the 28 pilot districts to all 72 districts in the country, and making Coartem® available in the private sector.

The other key challenge relates to the broader policy environment as well as the discount programme's pricing policy, in particular concerning the long term financing of the programme.

Leprosy

Remaining pockets of higher prevalence are attributed to refugee migration from neighbouring countries in conflict, where leprosy programmes have not been so successful. The challenge now is to secure progress in reducing prevalence in these areas.

Consideration of other tropical disease drug access PPPs

Lymphatic filariasis

Zambia is in the endemic zone for lymphatic filariasis (LF). However, there is little current evidence on the distribution and prevalence of the disease, and Zambia is not participating in the global LF drug donation programme.[1] A recent survey sought to collect data on the status of LF in 16 districts that had previously reported some form of filariasis, in order to decide whether to conduct a national survey and participate in the global programme for the elimination of LF. The results suggested that three of the surveyed districts – Kalabo, Luangwa and Sinazongwe – had some cases of LF. Kalabo recorded 130 positive cases (53%) out of the people tested with valid cards, Luangwa 85 positive cases (33%), and Sinazongwe 3% positive cases out of 276 volunteers tested. The survey report recommended that these results be verified by parasitological methods.

[1] In 1997, GlaxoSmithKline signed an agreement with WHO to donate all the albendazole required for the elimination of lymphatic filariasis. In 1999, Merck made a commitment to donate all the Mectizan® required for as long as required to eliminate LF in African countries where onchocerciasis and LF are co-endemic.

Sleeping sickness

CBOH and health personnel also suggested to the study team that there might be a case for considering a national prevalence study for Human African Trypanosomiasis (sleeping sickness), although WHO currently rates Zambia as a low endemic country. The WHO country office in Zambia has expressed interest in assisting government in such a study and, if shown to be appropriate, any subsequent application for donated drugs.[1]

[1] For sleeping sickness, Aventis has a Memorandum of Understanding (MOU) with WHO to donate supplies of pentamidine, melarsoprol, and eflornithine from 2001–2006, and Bayer has an MOU with WHO to donate supplies of suramin and nifurtimox from 2002–2007.

4. Drug access PPPs for HIV/AIDS in Zambia

Background information on the HIV/AIDS (Viramune® and Diflucan®) PPPs in Zambia

Zambia participates in two global PPPs related to HIV/AIDS – Boehringer Ingelheim's Viramune® Donation Programme and Pfizer's Diflucan® Partnership Programme.

Zambia does not participate in the UNAIDS-pharmaceutical industry Accelerating Access Initiative (AAI). Until 2002, when the government took the decision to make ART available in the public sector, treatment and care focused on home-based care, human rights promotion and access to treatment for opportunistic infections (OIs), ARVs were only available through the private sector and an estimated 2,000 people were paying privately for treatment.

In 2002, the government allocated US$ 3 million for the purchase of ARV drugs for 10,000 people living with HIV/AIDS. Two pilot sites were established at Lusaka's University Teaching Hospital (UTH) and Ndola Central Hospital. The programme has since expanded to nine provincial centres and, as of March 2004, nearly 3,000 PHA had accessed the government ART programme with all nine provincial sites and Lusaka UTH providing some services. The majority of these are using Triomune, a relatively cheap generic combination therapy procured from Cipla in India.

In 2003, Zambia embraced the WHO 3-by-5 ART initiative, under which it has increased its target for ART access from 10,000 to 100,000 by the end of 2005, when ART should be available in all 72 districts. This target will be achieved through public, NGO and private sector facilities, with the government providing training, capacity building and support to all sectors. There will be a certification process and accredited facilities will have access to government-procured drugs (primarily generic ARVs) under the reduced prices available

Table 6. Global HIV/AIDS PPPs in Zambia

	Prevention of mother-to-child transmission (PMTCT)	Treatment of Opportunistic Infections (OIs)
Global PPP programme and objective	Viramune® Donation Programme: to make nevirapine available free of charge to those most in need of it for PMTCT of HIV-1.	Diflucan® Partnership Programme: to make fluconazole available, free of charge, without money or time limits for HIV/AIDS patients for the treatment of cryptococcal meningitis and oesophageal candidiasis.
Drug donation	From July 2000, Boehringer Ingelheim (BI) announced the donation of Viramune® free to prevent mother-to-child transmission until 2005. As of August 2004, BI had provided more than 320,000 doses to 116 programmes in 54 countries. BI has confirmed that the donation will be extended beyond 2005.	In June 2001, Pfizer expanded programme eligibility from South Africa to the 49 Least Developed Countries where HIV/AIDS is most prevalent. In 2003, Pfizer expanded eligibility criteria to include all developing countries with HIV/AIDS prevalence greater than 1%.
Conditionalities	Nothing unreasonable. Axios handles the application and review process on behalf of BI. Annual progress reports and monthly requisitions of drugs.	Applications are screened by Axios and a panel of experts on a range of issues including diagnostic ability of prescribers, diagnostic facilities available, health information and inventory management. Approved recipients need to use drugs for the indications within the limitations of the donation, report six-monthly or when re-supply is needed, report diversions and pay for charges after receipt at port of entry, permit Pfizer to audit any facility and provide the drug free of charge to the patient.

to the public sector. Although Zambia is eligible for discounted or 'cost price' offers from the pharmaceutical industry, generic ARVs remain much more affordable, especially the combination therapies now available. There are no formal PPPs addressing access to ARVs in Zambia, and all ARVs are procured through international competitive tenders.

Key findings

Table 7 summarises the programme objectives and performance of the two PPPs for HIV/AIDS. More detail on national policy and programmes is provided in Annexes 5 and 6.

Table 7: Summary indicators of impact of HIV/AIDS PPPs in Zambia

PPP Indicator	Viramune® Donation Programme	Diflucan® Partnership Programme
Programme objective	To make nevirapine available for PMTCT in Zambia.	To make fluconazole available free of charge for HIV/AIDS patients for treatment of cryptococcal meningitis and oesophageal candidiasis. (To date the Diflucan® donation has been of the 200mg tablet; the oral suspension and intravenous solution are currently not available to Zambia.)
Programme initiation	During 2001, Boehringer Ingelheim initiated several pilot projects. In liaison with Axios, Zambia decided to centralise PMTCT programmes at CBOH After May 2003.	Through MOH/CBOH: May 2003 (MoU); first consignment and training, June 2003. Through CHAZ: mid-2003 (MoU); first consignment, September 2003; first training, March 2004.
Population eligible	All HIV-positive mothers in the public sector.	HIV/AIDS patients in the public sector with cryptococcal meningitis and oesophageal candidiasis.
National partners	CBOH NAC Centre for Infectious Disease Research (CIDRZ) Columbia University AED-Linkages USAID UNICEF	CBOH CHAZ
Current national budget contribution	Procurement from Axios by national reproductive health specialist; drug supply through MSL and district system; district focal points and reporting.	Donation is free of charge without money or time limits as long as conditionalities are adhered to; also commitment for enrolled patients.
Current national coverage	By March 2004 there were 75 PMTCT sites in 11 districts, mostly in partnership with earlier pilot sites. During May–October 2003, 1,968 adult and 1,434 infant doses were prescribed nationally.	MOH/CBOH: 10 facilities (provincial hospitals in nine provinces with two in the Copperbelt province). CHAZ: 11 facilities.
Reporting system	Clinics' monthly reports to CBOH are collated, with support from CIDRZ, and sent to Axios with request for more supplies.	Reporting to CBOH or CHAZ in order to receive new supplies. No reporting schedule: reports are submitted to receive new supplies. Both CBOH and CHAZ stated that they want to require monthly reporting from facilities. CBOH and CHAZ consolidate reports and submit to Axios. Reports required 6 monthly or when re-supply is requested if sooner.
Performance against targets	May–October 2003 in pilot districts: 20% ANC receiving VCT (target 70% in all districts by 2005). 38% HIV-positive mothers and 28% infants receiving Viramune® (target 75% by 2005).	No information.
Sustainability	BI commitment unclear beyond 2005; maybe overtaken by events as Zambian ART availability precludes single dose monotherapy.	Donation is non-money and non-time limited providing conditionalities are adhered to.

Country priorities

Until recently, political support for efforts to tackle HIV/AIDS in Zambia was relatively weak and mechanisms for accountability and collaboration between key government sectors to support a multisectoral approach were inadequate (MOH 2004). Since 2000, there has been greater political commitment and HIV/AIDS receives special priority in health plans.

The Zambia Poverty Reduction Strategy Paper (PRSP) identifies HIV/AIDS as the country's most important cross-cutting development issue and notes that the epidemic has reversed the social and economic gains made since independence. HIV/AIDS is a specific budget line within the PRSP with an allocation of US$ 94.6 million (nearly 8% of the total) (Lake 2004). The goals for HIV/AIDS within the PRSP include measures to reduce new infections, promote positive and healthy living among asymptomatic PHA, improve the quality of life of those with AIDS, improve the quality of life of orphans, and strengthen monitoring, evaluation and surveillance systems.

A Committee of Ministers on HIV/AIDS/STD/TB heads the administrative structure governing development and implementation of HIV/AIDS policy. In 2000, this committee established the NAC and Secretariat to lead policy development and a number of specialised Technical Working Groups (TWGs). In 2000, the NAC published the National AIDS Policy and HIV/AIDS/STD/TB Strategic Plan 2001–2003. The NAC has since published a second Strategic Plan and budget for 2002–2005. In 2002, a National Action Plan for implementation of AIDS-related activities was adopted. Two of the TWGs cover PMTCT, and treatment, care and support.

To implement the Strategic Plan, focal points were identified in each Ministry and at provincial and district levels to coordinate HIV/AIDS programmes and build capacity for implementation. Within the CBOH, an HIV/AIDS Committee was established in 2003. The private sector and NGOs have also been mobilised and there is a Country Coordinating Mechanism to oversee GFATM applications and implementation. Key critical issues include the impact of the epidemic on the demand for health care and the supply of health workers, and the lack of a clear division of responsibility for HIV/AIDS policy development and implementation between the NAC and CBOH.

The 2001–2005 National Health Strategic Plan outlined a new HIV/AIDS strategy, incorporating mobilisation of national leadership, a multisectoral approach and policy, development of national guidelines, integration of health sector activities in existing systems to strengthen coordination, tracking of social and cultural barriers to implementation, strengthening prevention and care of OIs as well as home-based and orphan care, and enhanced mobilisation of financial resources.

The government has also identified geographical and social priority areas, the former including towns with regular cross-border trading and the latter in and out of school youth, commercial sex workers, and public and private sector workers (HIV/AIDS in Zambia, 1999).

In 2004, the government developed a policy and operational guidelines to scale up ART in Zambia, reflecting the advent of additional funding from sources such as the GFATM, World Bank MAP 2 and US President's Emergency Plan for AIDS Relief (PEPFAR).

Prevention of mother-to-child transmission

Prevention of mother-to-child transmission is a key priority for the Zambian government. An estimated 30–40,000 children are infected through mother-to-child transmission each year and paediatric HIV/AIDS has reversed recent improvements in infant and child mortality.

Efforts to prevent mother-to-child transmission started in 1999 with a pilot programme funded by UNICEF and a number of NGOs. In 2002, the CBOH began a programme to scale up PMTCT services and the initiation of drug donation to a central point at the CBOH catalysed the integration and coordination of these efforts into a broader national strategy. In 2003, a strategy and guidelines were published detailing the scaling up of the PMTCT programme to national level.

The goals of the Strategic Framework for the Expansion of PMTCT Services 2003–2005 are to expand PMTCT to all 1,284 MCH facilities in 72 districts by 2005, provide VCT to 70% of women at the first ANC visit, provide ARV monotherapy (zidovudine or nevirapine) to positive women and increase the proportion of women who exclusively breastfeed for six months to 70%. These goals will be achieved through primary prevention both of HIV and pregnancy, PMTCT among HIV-positive mothers, expanding community care and sup

port, and establishing referrals to other relevant programmes. Currently the programme is active in 75 sites in 11 districts, mainly those which previously had pilot projects. Scaling up beyond these 11 pilot districts may prove more difficult.

PMTCT policy is evolving rapidly with the increased availability of ARV triple therapy, which may render single dose monotherapy for PMTCT inappropriate due to the potential for development of resistant strains. This is a particular problem for nevirapine, to which the virus may become resistant after only one dose. In 2004, it is likely that the PMTCT TWG will recommend a change in policy from monotherapy to triple (or at a minimum dual) therapy for PMTCT. Such a policy shift will mean that the Viramune® Donation Programme would only remain a priority in Zambia if nevirapine were used as a component of dual or triple therapy for PMTCT and Boehringer Ingelheim (BI) agreed to its donation being used in this way.

Treatment and prevention of opportunistic infections (OIs)

Prevention and treatment of OIs arising from HIV infection is also a key priority for the Zambian government. Fluconazole is a useful drug for the treatment of oesophageal candidiasis and in the life long prophylactic therapy maintenance after treatment for cryptococcal meningitis (amphotericin B is recommended in the forthcoming national treatment guidelines as the drug of choice for the acute phase).

Guidelines for the treatment of OIs were developed in 2001. These have since been revised and are currently being finalised. A training package on the management of OIs has been developed and is also in the process of being finalised. The revised guidelines were not available for review, so it was not possible for this study to assess their content with respect to treatment of cryptococcal meningitis and oesophageal candidiasis. However, the Diflucan® Partnership Programme is therefore likely to remain a priority in Zambia.

Ownership and governance of drug access PPPs

Viramune® Donation Programme

In 2002, a reproductive health specialist was appointed in the Public Health Directorate of the CBOH with responsibility for coordinating existing efforts and developing the national PMTCT national strategy. This required bringing together the NAC PMTCT TWG and the different agencies, NGOs and mission organisations involved in implementing pilot projects. Initially, BI provided donations, negotiated internationally, directly to organisations implementing pilot projects, but this ceased in 2003 when the Viramune® Donation Programme was centralised within the CBOH. CBOH liaises with Axios and has no direct contact with BI.

The shift from separate small scale pilot projects to an integrated larger scale programme, and from direct donations to a centrally managed donation programme created some challenges, in terms of building consensus and ownership and promoting communication and coordination between the different stakeholders. An additional challenge was ensuring that all projects provided a comprehensive range of high quality antenatal care interventions and were able to monitor PMTCT drug effectiveness, adherence and resistance.

In 2002, the NAC PMTCT TWG was disbanded and the CBOH became the focal point for development, coordination and implementation of the new programme. The TWG was reconstituted at the end of 2003, with responsibility for developing policy, coordinating future interventions and fostering local, national and international networks on PMTCT in collaboration with the CBOH. The PMTCT programme will remain the responsibility of the CBOH and will be reviewed by the Health Information System Unit and the reproductive health specialist using routine monitoring systems and annual programme reviews. However, reporting and accountability for policy decisions remain convoluted, with the Chair of the TWG reporting to the NAC and the Secretariat reporting to the CBOH.

Diflucan® Partnership Programme

In May 2003, a memorandum of understanding was signed between Pfizer and the MOH. The Director of Clinical Services at the CBOH is responsible for HIV/AIDS treatment and care, including ART and management of OIs. This includes the Diflucan® Partnership Programme, for which day-to-day operational responsibility rests with the Assistant to the Pharmacy Specialist. Management at facility level is generally by the pharmacist in charge of the ART programme.

Integration with general health services

Viramune® Donation Programme

In 2002, the CBOH initiated communication with Axios to request nevirapine through the Viramune® Donation Programme. To start the programme, Axios required current data on number of women registered, counselled and receiving test results and information on the programme context, potential barriers to implementation, and drug systems. Prior to this, both BI and Axios had relied on data from pilot projects to predict demand in Zambia.

Attempts were made to integrate information collection with the regular Health Management Information System (HMIS). However, since the HMIS is overstretched, the programme maintains a separate information system on demand, supply and impact. The national programme manager reports demand to Axios although, in the early stages of the programme, this was difficult to predict. Axios requires clinic data on a monthly basis, which requires separate collection of information as clinics usually only produce quarterly reports. The programme receives support with collating, summarising and analysing the data from the Centre for Infectious Disease Research in Zambia (CIDRZ).

The first supply was received in May 2003 and used in June 2003. Procurement takes place through Axios and the drugs are delivered to the reproductive health specialist in the CBOH, who passes them directly to MSL. Clinic requirements are reported to and processed by the CBOH, in order for Axios and MSL to supply the clinics. After an initial problem, when Axios delivered only half the order and the drugs ran out, the programme has been on track. However, the system does not allow buffer stocks to be maintained in country, which has implications for stock control and stock outs.

Integrating Viramune® distribution into the drug supply system has been complex, involving multiple actors and functions. The BHCP uses a drug kit pre-packed according to tender specifications, which means that it is not easy to incorporate additional drugs. As noted earlier, there have been problems related to integration of the pilot projects into the MSL system and to the MSL schedule for distributing drugs to districts. If a clinic runs out between scheduled distribution times, there is only a small district revolving fund available to purchase supplies separately. As a result, some clinics order more stock than they need and drugs expire. Some clinics have requested extra supplies in order to provide the drugs to women in the first trimester of pregnancy. This is problematic since an early evaluation found that 60% of women given the drug this early on did not use it for themselves or their babies and this approach misses those who seroconvert later in pregnancy.

Incorporating effective estimates of demand has been challenging. Data on HIV testing in MCH settings is not included in the routine VCT information system, which is managed by the CBOH laboratory department. Coordinating the programme's requirements with other demands on the laboratory infrastructure has also been challenging, with early supplies of test kits donated through Axios being absorbed into the general VCT system, rather than being distributed to the MCH clinics they were destined for. Furthermore, the national VCT programme did not include estimates of testing of pregnant women and was not allocating sufficient tests to these clinics.

Diflucan® Partnership Programme

There are two separate arrangements for providing Diflucan® to Zambia, one with the MOH and CBOH and one with CHAZ. The MOH received its first consignment in June 2003 and CHAZ in September 2003. The CBOH currently distributes Diflucan® to 10 provincial hospitals, including two in the Copperbelt Province, and CHAZ distributes to 11 mission hospitals. Distribution of Diflucan® to the provincial hospitals started after the first train-ing for health workers in these facilities was conducted in June and July 2003. Distribution to mission hospitals started after training for health workers in CHAZ facilities was conducted in March 2004.

Diflucan® is distributed as part of the mainstream drug supply system. The programme requires the use of dedicated drug management tools and reporting requirements are beyond those required for normal drug management. Orders are processed upon receipt of the utilisation report in addition to the normal requisition requirements. At national level, the programme needs to be able to report on use by all 21 facilities to place an order, and compiling this information requires following precise instructions including regular reporting. This is problematic since, in practice, facilities report only when replenishment is required. How ever, in Zambia, reporting requirements are less

demanding than in countries where the programme was operational earlier.

These practical difficulties, in addition to the fact that this is a relatively new programme with little historical usage information, mean that ensuring uninterrupted supply to patients is a challenge. In addition, as the programme expands, efficient management using the required reporting system will represent a significant workload for the Procurement Unit of the CBOH and CHAZ and for districts and hospitals and districts.

The programme also requires that the donation be used for HIV/AIDS patients presenting with cryptococcal meningitis and oesophageal candidiasis, confirmed through laboratory testing. Confirmatory testing for cryptococcal meningitis and oesophageal candidiasis is only possible in tertiary facilities in Zambia, and this requirement may delay treatment and limit the number of facilities able to provide treatment. Although reasonable surety on the part of the prescriber as to the likely diagnosis should be sufficient to commence therapy, it appears that Pfizer will continue to insist on maintaining this requirement.

Health and health systems impact

Viramune® Donation Programme

The programme is currently operational in 75 sites in 11 districts, mainly in urban areas and in sites that were previously implementing pilot projects. Secondary and tertiary hospitals have only just started to receive drugs under the donation programme, since the pilot sites were all in primary health care centres. Of the four districts visited in this study, Viramune® was available in two – Lusaka Urban and Ndola (Table 8).

Between May 2003, when the programme started, and October 2003, 1,968 adult and 1,434 infant doses of Viramune® were prescribed. Most women in urban areas deliver their babies in facilities, which make them easy to reach, but scaling up the programme in rural areas where 80% of women deliver at home will be challenging. The programme is considering adopting mother-baby nevirapine packs, although there are problems with administering the infant dose, which may become unstable once in a syringe and which has to be determined by the weight of the infant.

Table 8: Activities of Viramune® Donation Programme in districts in Zambia

District	Ndola	Lusaka Urban
Drug distribution	Through the district pharmacy, in partnership with the USAID Linkages project, which had received Viramune® directly from BI since 2002.	Through DHMT, to district pharmacy, in partnership with CIDRZ, Elizabeth Glaser Foundation, USAID Linkages, JICA. Until 2000, zidovudine donations through UNICEF. Viramune® also obtained directly from BI under a contract with the DHMT and CIDRZ. CIDRZ and DHMT clear supplies at airport and deliver to district pharmacy.
Level of availability of Viramune®	Viramune® given to mothers at 32 weeks gestation through ANC at 16 health centres, infant dose after birth. 70% of mothers deliver in clinics – of whom approximately 30% HIV-positive. Available in Ndola Central Hospital wards from DHMT but not through pharmacy (although they have ARVs).	Viramune® adult dose given to mothers at first ANC appointment, infant dose at birth. 92% of mothers deliver in clinics. Stock outs on two occasions in 2003.
Achievements	Coordinated programme integrated with the district health system. MSL distributing drug. Missions are entering the programme.	800–1,000 adult doses annually. Well supported by external partners. Research with CIDRZ on adherence, resistance and effectiveness. Linking to PMTCT Plus ART initiative.
Reported challenges	Ensuring infant receives dose. Community awareness of programme. Adverse effects and resistance from monotherapy. Communication with VCT and ART services.	Integrated drug management system on paper but shift to centralised programme at CBOH led to stock outs so have had to maintain their own system. Two sets of supplies require separate deliveries, stock management, reporting. Costs of reporting high but less than purchasing high volumes of generic nevirapine. Stigma linked with HIV-positive status reduces uptake.

Diflucan® Partnership Programme

Both the CBOH and CHAZ programmes have been operational for less than six months. The 10 provincial hospitals are involved through the CBOH-managed programme, and the 11 mission hospitals through the CHAZ-managed programme. A total of 53,396 200mg tablets have been distributed to the 10 provincial hospitals since September 2003.

Further expansion will be linked with the roll out of ARVs, primarily because of the cost savings in delivering training on clinical indication restrictions and drug management requirements of the Diflucan® programme together with training required to roll out of ART.

Sustainability

Viramune® Donation Programme

The main cost to the public sector of the Viramune® Donation Programme is the coordination role played by the reproductive health specialist in the CBOH. While the programme has successfully integrated a wide range of previously disparate pilot projects, there are serious concerns about management capacity, since the specialist is also responsible for other reproductive health programmes such as family planning and youth sexual health services. MSL incurs charges for clearing packages of drugs and distribution costs, which are based on estimates of drug value provided by Axios.

Further costs are incurred at district level in dedicated systems for stock management, data gathering at clinics and collating monthly reports. In addition, the start-up costs of training and informing the community of the programme are high. However, these costs are generally thought to be less than the potential cost of procuring high volumes of generic nevirapine on the open market.

The PMTCT programme would probably be functioning even in the absence of Viramune® donation, because of the number of external partners interested in PMTCT. However, with regard to the donation programme, there are concerns about the risk of resistance developing with the use of single dose monotherapy prophylaxis for those who may need to access triple therapy under the ART programme. More research is needed into the effectiveness and resistance implications of short-term use of triple or dual therapy before shifting from nevirapine, which is known to be simple and highly cost effective.

The PMTCT Technical Working Group is likely to recommend a policy shift to triple or dual therapy for PMTCT in the near future. This may have implications for the Viramune® Donation Programme, which would no longer be a priority for Zambia unless nevirapine is used as a component of therapy and BI agrees to its donation being used in this way. Questions about the sustainability of the programme may be rendered redundant if there is a policy shift to triple or dual therapy for PMTCT, using generic ARVs.

Diflucan® Partnership Programme

Overall, the programme is felt to be sustainable, given the comparatively small numbers treated, although the use and reporting requirements do represent costs to the system. The main cost to the public sector of the Diflucan® Partnership Programme is the coordination function within the Directorate of Clinical Services at the CBOH, and the drug management and reporting requirements at MSL and participating facilities. As the programme scales up, the time required for coordination by the CBOH will increase significantly if the requirement for collecting usage information for all participating facilities before a national order can be placed with Axios is maintained, and obtaining and processing reports from all facilities in all districts is likely to be impractical. The MOH incurs clearing charges for the packages of drugs and distribution costs, which are based on estimates of drug value provided by Axios.

Further costs are incurred at district level in dedicated systems for stock management, data gathering, and reporting to the CBOH as part of the replenishment requirements. Expansion of treatment of cryptococcal meningitis to additional facilities will require an expansion of laboratories facilities for confirmation of diagnosis and associated costs, if Pfizer maintains this condition.

Anther significant cost is the requirement for clinical and drug management training to ensure that prescribers only use the drug within the limited indications of the donation and fulfil the specific requirements for managing and replenishing supplies. This has delayed the expansion of the programme, resulting in the strategy, discussed above, to integrate Diflucan® training with training for scale up of ART.

Perceived benefits

Viramune® Donation Programme

It was reported that the costs of procuring generic nevirapine would be higher than the costs of managing the donation programme. ARVs are becoming available under the national ART strategy but progress has been slow and, in the meantime, the donation remains a convenient means of ensuring regular and adequate supply of nevirapine. In addition, Axios was reported to have provided valuable support to the programme manager in navigating institutional constraints and estimating demand.

In some districts, donor-funded projects are embarking on PMTCT Plus, where mothers who have received prophylactic ARVs and their families will be eligible for free ART. The PMTCT programme, supported by the donation programme, provides a valuable entry point for ongoing ART for women and their families. However, referral links to the ART programme, which is currently only in tertiary provincial hospitals and under which patients must pay for treatment, remain weak.

Diflucan® Partnership Programme

Without the donation programme it is likely that anti-fungal medication for cryptococcal meningitis or oesophageal candidiasis would only be available sporadically and in a few facilities since all the options are expensive. Even if Zambia realises its plan to make available amphotericin B for the acute phase of cryptococcal meningitis, continued availability of fluconazole for the maintenance phase and for treatment of oesophageal candidiasis will provide a life-saving and life-improving intervention for affected patients.

Outstanding challenges

Viramune® Donation Programme

Although Axios has been supportive to the MOH, there is a perception that Axios' internal review process lacks insight into the specifics of the Zambian health system. More importantly, the significant reporting requirements are only feasible with external assistance and have opportunity costs for other reproductive health programmes. It was also reported that Axios has downplayed the potential drawbacks of using nevirapine – including side effects and resistance – and provides no mechanism for reporting such events.

Other challenges to the PMTCT programme relate more to the broader policy environment than to the donation programme. These challenges include:

- Fostering demand for VCT among pregnant women.
- Encouraging women to deliver in facilities.
- Ensuring that babies born outside facilities receive their dose.
- Providing sensitive support for women's infant feeding choices.
- Managing the policy transition to triple or dual therapy for women who may want subsequent access to ART.
- Improving communication between the PMTCT programme and other areas of HIV, reproductive health and child health policy.

Diflucan® Partnership Programme

In contrast with nevirapine monotherapy for PMTCT, fluconazole is likely to remain the drug of choice for the maintenance phase of cryptococcal meningitis and for the treatment of oesophageal candidiasis, and demand for use will increase. Expansion will, however, create significant management challenges at central level and operational challenges at facility level, in terms of use and reporting requirements, if the programme continues as it is currently designed. These challenges include:

- Clinical limitations on use of donated Diflucan® (for the two indicated conditions), which cannot be used for other indicated fungal infections.
- Requirement for laboratory confirmation of diagnosis versus diagnosis based on clinical presentation, which currently restricts treatment to a limited number of facilities.
- Feasibility of separate reporting systems when the programme is scaled up to all districts, including the requirement to report on usage in all participating facilities for reordering for the overall programme.
- Funding the training required to fulfil donation programme conditions as the programme is scaled up.

5. Summary findings and conclusions

Tropical disease PPPs: malaria, leprosy and other diseases

- Governance of, and decision-making within, the PPP-assisted national tropical disease programmes rests at national level, and the PPPs comply with criteria established by the global disease partnerships. The study found no evidence of unreasonable conditionalities for these two tropical disease drug access PPPs in relation to the scope of the programme, drug indications or modes of operation.

Malaria

- Malaria is a serious public health problem in Zambia, with high resistance to chloroquine (CQ) and emerging resistance to sulphadoxine-pyrimethamine (SP). In November 2001, with support from WHO Roll Back Malaria (RBM), the Ministry of Health (MOH) and Central Board of Health (CBOH), Zambia adopted combination therapy artemether-lumefantrine (Coartem®) as the first-line drug for treating uncomplicated malaria, an effective drug for the treatment of malaria where resistance is a major concern.
- The Coartem® programme is currently supported by Novartis and GFATM, with ongoing technical support from WHO RBM. Coartem® is procured for Zambia by WHO, with funds from the GFATM. Governmental policy commitment to the Coartem® PPP is very substantial, although there were reports that some donors had concerns about the relatively high cost of the drug and longer-term sustainability. It would be difficult for Zambia to finance provision of Coartem®, in the absence of significant price discounts, and financial support from the GFATM. In the longer term, sustainability will depend on inclusion of Coartem® in the national health budget and support from Zambia's traditional development partners, as grants from GFATM are likely to sustain procurements for only the next three to five years.
- The programme is being implemented in 28 pilot districts, and plans, as set out in the GFATM proposal, to expand coverage to all 72 districts by end 2004. This is ambitious and poses logistical challenges, in terms of providing sufficient training in use and forecasting of Coartem®. Drug management and distribution is now fully integrated into the mainstream drug distribution system and Health Management Information System. The discount programme specifies reasonable conditionalities, concerning inclusion in treatment guidelines, effective distribution, and prevention of diversion and reporting. A key challenge will be to ensure a constant supply of Coartem® as the programme is scaled up.
- Staff at national and district levels perceive that the Coartem® initiative has the potential to benefit patients with chloroquine-resistant malaria and to strengthen health system capacity in pharmacovigilance. It has also motivated the MOH to improve prevention and diagnostic aspects of malaria control.
- Given the high value of the drug, and growing demand for it, there is a risk of diversion of Coartem®. Stocks in public facilities and private pharmacies will need to be monitored carefully, and anti-diversion measures put in place. Programme conditionalities imply that repeated product diversion to unauthorised private providers could result in product withdrawal. It will be important to monitor how any diversion incidents will be dealt with in practice by the government and WHO-Novartis.
- The Coartem® programme was introduced in early 2003, and it is too early to assess overall health and health systems impact. The study suggests that a review in due course to draw on greater experience at country level of the

Coartem® discounted price agreement for malaria could be of benefit, since it potentially raises significantly different issues from the drug donation PPPs, in relation to market impact and sustainability.

- Between 50% and 60% of patients seek malaria treatment from the private sector, which poses major challenges for the delivery of effective care with quality drugs. Under WHO-Novartis agreement conditions, the product can be distributed by authorized private providers, so long as the price is not 'unduly raised'. The CBOH's pilot social marketing programme, intended to expand access to Coartem® at a reduced price through selected pharmacies and retail outlets, is an important initiative, and will provide valuable lessons in developing best practice in improving access to treatment through the private sector.

Leprosy

- There has been a long-standing leprosy control programme in Zambia, dating back as far as 1932. Based on the WHO definition, 100% coverage with MDT had been achieved, and leprosy eliminated at national level, prior to the initiation of the WHO-Novartis agreement in 1999. Sustainability is not a major issue, since leprosy is a comparatively small-scale problem and the national Leprosy Programme benefits from good collaboration between the CBOH and Churches Health Association of Zambia (CHAZ) as well as support from international agencies.
- The MDT donation programme uses an adapted MOH and CBOH ordering system for all drugs purchased through WHO and the drugs are distributed through the mainstream drug distribution system. During district visits, the study team found no evidence to suggest that this drug access PPP distorts government priorities or the allocation of human or financial resources.

Other tropical diseases

- With respect to other tropical diseases, the study team found some indications that the availability of support from the range of drug access PPPs may not be as widely known as is desirable. A 2003 survey suggested that there were cases of lymphatic filariasis in three of the 16 districts surveyed. Further epidemiological investigation has been recommended to inform any future government decision on whether Zambia should apply for donated drugs for lymphatic filariasis. WHO has expressed interest in assisting the government to assess national prevalence of sleeping sickness, to determine whether an application for donated drugs is appropriate.

HIV/AIDS PPPs: Viramune® and Diflucan®

Zambia is experiencing a generalised HIV/AIDS epidemic. The government has set out strategies for prevention and treatment, including a target of 100,000 people living with HIV/AIDS (PHA) on antiretroviral therapy (ART) by the end of 2005. The current per capita drug budget (including for antiretroviral drugs) is approximately US$ 3.50 and, while the government invested US$ 3 million in 2003 in procuring antiretroviral drugs (ARVs), the figure for 2004 may be lower due to fiscal constraints. However, the country is likely to benefit from new sources of external funds for treatment including the GFATM, World Bank Multisectoral AIDS Programme (MAP) and US President's Emergency Plan for AIDS Relief (PEPFAR).

Zambia did not participate in the Accelerating Access Initiative (AAI), and is purchasing generic fixed dose combination drugs for anti-retroviral treatment. Zambia currently participates in two global PPPs related to HIV/AIDS, Boehringer Ingelheim's Viramune® Donation Programme and Pfizer's Diflucan® Partnership Programme. Prevention of mother-to-child transmission (PMTCT) and treatment of opportunistic infections (OIs) are priorities for the Zambian government.

Viramune® Donation Programme

- The national PMTCT programme, launched in early 2003, covers 11 districts, mainly in urban areas, building on earlier pilot project sites run by partners including UNICEF, AED Linkages and the Columbia University Centre for Infectious Disease Research in Zambia (CIDRZ). The national programme aims to cover all 72 districts by the end of 2005, with 70% of pregnant women receiving VCT services and 75% of HIV-positive mothers and their infants receiving prophylactic ART.
- The Viramune® Donation Programme started to deliver drugs to the CBOH in May 2003, under a contract managed by Axios on behalf of Boehringer Ingelheim (BI), and BI intends to

extend the donation programme beyond 2005. Prior to centralisation at CBOH, several PMTCT projects had independent contracts with BI at international level. A key challenge for the government programme has been incorporating and coordinating these disparate initiatives without disrupting their drug supplies, and parallel systems continue in some areas.

- Integrating Viramune® distribution into the drug supply system has been complex, even with the support that has been provided to assist CBOH. While there are no unreasonable conditionalities, the programme has substantial monthly reporting requirements as part of the drug requisition process, and a separate information system on demand, supply and impact is maintained since the HMIS is overstretched. However, the national programme manager maintains that the costs of reporting are more than offset by the savings on buying high volumes of generic nevirapine on the open market.
- The programme is functioning fairly successfully, but has yet to scale up to national coverage. This will require improved cooperation between different stakeholders, including the different departments within the CBOH and National HIV/AIDS/STI/TB Council PMTCT Technical Working Group, as well as strategies to reach women in rural areas who do not deliver in health facilities.
- There are concerns about the lack of evidence on the risk of resistance developing with the use of single dose monotherapy prophylaxis for those who may want to go on to access triple therapy under the ART programme. The PMTCT Technical Working Group is likely to recommend a policy shift to triple or dual therapy for PMTCT in the near future. This may have implications for the Viramune® Donation Programme, which may no longer be a priority for Zambia unless nevirapine is used as a component of triple therapy and BI agrees to its donation being used in this way.

Diflucan® Partnership Programme

- The Diflucan® Partnership Programme offers a useful treatment for oesophageal candidiasis and life-long prophylactic maintenance of cryptococcal meningitis that might not otherwise be available, and is likely to remain a priority in Zambia. However, fluconazole is not the drug of choice for the acute phase of cryptococcal meningitis in Zambia. Conditions with regard to use of Diflucan® include strict clinical indications – which requires additional training – and laboratory confirmation – which is only available in tertiary facilities limiting the number of patients who can access treatment.
- Diflucan® is provided through two separate arrangements, with the CBOH and with CHAZ, but is distributed as part of the mainstream drug supply system. The programme requires the use of dedicated and complex drug management tools and reporting requirements that are beyond those required by the mainstream system. National ordering for the programme overall depends on being able to compile reports from all the 21 facilities currently receiving Diflucan®. If reporting is inadequate, this has implications for the national requisition process, which could result in stock outs and treatment interruptions. Efficient management will be an increasing challenge as the programme expands and it is suggested that reporting requirements are reviewed to reduce their complexity and dependence on 100% individual facility reporting.

Annexes

ANNEX 1

Terms of Reference for Phase II studies

Background

The health consequences of poverty lead to major health inequities for poorer populations in developing countries. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled by public sector or NGOs independently.

In recent years, a number of collaborations have arisen to tackle specific problems. These are usually targeted to specific products, diseases or technologies. One particular group of these public-private partnerships (PPPs) addresses access to pharmaceuticals (usually drugs) that are critical to treatment or care for tropical diseases, which disproportionately or uniquely affect the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated, heavily discounted or in some way subsidised by their producer (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications. These access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis, trachoma and sleeping sickness compared with HIV/AIDS, tuberculosis, and malaria). They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide.

Other types of PPP have been established to encourage pharmaceutical companies to reduce the prices of (and sometimes donate for free) drugs that treat diseases which exist in both rich and poor countries – for example, HIV/AIDS and malaria. Here, the multi-partner initiative generally focuses on negotiating different (or tiered) prices across markets – with the most preferential prices reserved for public sector services in developing countries, which are assumed to be accessed by the poorest. These types of initiative have generated more controversy due to the difficulties of establishing what are considered to be 'fair' prices in different markets and the problem of arbitrage – or leakage between those markets. Furthermore, they are more difficult than the drug donation programmes above to classify as 'PPPs', since they are not necessarily distinct from normal government purchaser-pharmaceutical provider contracting processes (such as NHS bulk purchasing arrangements) and are heavily influenced by the presence (or not) of generic equivalent products in the market. A framework (Appendix A) has been developed to show the different means by which pharmaceutical companies reduce prices in the area of HIV/AIDS.

Both types of PPP raise a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key question is the degree to which the involvement of multinational R&D pharmaceutical companies in some stage of drug procurement and delivery facilitates better drug availability and access by the poor. Further questions include whether the availability of free or reduced price drugs distorts decisions on priorities or prices, what the feasibility is of taking such initiatives to scale, and their sustainability. This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of debt relief, Sector-Wide Approaches (SWAps) in health, and multisectoral Poverty Reduction Strategic Plans (PRSPs). Issues of integration, coordination, implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

The UK Department for International Development (DFID) is funding the Initiative on Public Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to con

duct a series of studies across a range of access partnerships and countries.

Phase I: Pilot study in Uganda, 2003 (completed)

A pilot study to assess the health and health systems impact of PPPs for improving access to pharmaceuticals in a selected low-income country was undertaken in Uganda in May 2003. It covered tropical disease programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness, and three HIV/AIDS PPPs: the UNAIDS Drug Access Initiative (DAI) and Accelerating Access Initiative (AAI); the Viramune® Donation Programme; and the Diflucan® Partnership Programme. The study also pilot tested a study protocol and research instruments for further studies. A full report on the pilot study is available.

Phase II: Three more country studies, a synthesis paper and dissemination

DFID is now funding IPPPH to:

- **Undertake three further country studies** including at least two studies of HIV/AIDS PPPs and two of selected tropical disease PPPs. The countries – Botswana, Sri Lanka and Zambia – have been selected to ensure that, together with the Uganda study, the maximum number of global drug access partnerships is examined, including major active tropical disease partnerships. The study in Sri Lanka will specifically examine whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.
- **Examine supranational level issues** including how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate (e.g. GAEL etc), and how they relate to the countries examined.
- **Prepare a synthesis paper** of all the work and conclusions, including the pilot study. The purpose of the synthesis paper is to compare and contrast for policy makers the potential implications, costs, benefits and risks of drug donations and discounted pricing schemes for contributing to expansion of access to appropriate treatment or control of diseases that primarily afflict poor populations. The synthesis shall also note for policy makers, pharmaceutical companies and other actors (such as NGOs or funders) operational options that can maximise health and health system benefits and reduce any potential undesirable impacts of such arrangements.
- **Develop and implement a dissemination strategy**, which will communicate the key findings, conclusions and recommendations of the studies to a range of relevant audiences including national policy makers, bilateral and multilateral aid funders, pharmaceutical companies and non-governmental agencies.

Objectives

The studies are part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access for those disadvantaged by poverty to life-saving pharmaceuticals. A key overall objective of the programme is to contribute to the identification of good practices that maximise health benefits for the poor and minimise problems and unintended negative consequences for health systems.

The specific objective of the current studies is to assess the health and health systems impact in the selected countries of PPPs for improving access to pharmaceuticals in relation to HIV/AIDS and to tropical diseases, where pharmaceutical companies are involved as partners at some stage of programme design and/or implementation. The key research question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates drug availability and access by the poor.

The studies should map the key features of the PPPs and examine the relationship between the specific drug donation or discount price programmes, the broader partnerships in which they participate and the countries examined. At country level, the studies will examine issues of ownership, regulation, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured (e.g. the World Bank's MAP, the GFATM or generic purchasing activities). They will review the PPPs in relationship to country health systems and the broader context, both vertically (e.g. how the PPPs relate

to pharmaceutical policies, donor/funding issues, broader partnerships) and horizontally (e.g. perceptions and impacts of the partnership from both PPP and government perspectives).

Key issues for examination should include:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.
- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available on the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and MIS/HMIS; government-NGO working relationships.
- For ARVs, the effects of different models of drug supply on regulation, drug procurement and drug distribution. In addition, their impact on equity of access and product availability/prices in both public and private sectors.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

A synthesis paper will summarise evidence from the studies of country level experience set within the context of country conditions and the global partnerships.

Another specific objective of this phase of work will be the wide and effective dissemination of the products from Phases I and II.

Outputs

The outputs for this second phase of activity will be:

- A report on findings from the examination at supranational level of the relationships between specific drug donation or discount price programmes, broader partnerships, and the countries examined (five days). This report should be completed and made available to country team members before the country studies begin.
- Individual reports on the three further country studies (12 working days in each country, plus preparation and report writing). Draft reports on the country studies should be completed by end March 2004.
- A synthesis paper covering all the work to date (11 days), which should be provided to DFID by the end of April 2004.
- Wide and effective dissemination of the products. This is likely to require tailoring for different audiences (e.g. national governments and partners, pharmaceutical companies, global programme partners, DFID and other agencies). Draft timetabled proposals for the dissemination strategy should be provided to DFID by end March 2004. For budgeting purposes it is assumed that the dissemination will include: printing two versions of the report (summary and full); a workshop for 30 persons in Geneva; presentations to four other events (e.g. Geneva, London and two non-European venues).

Methods

Rapid assessments: These are rapid assessments rather than detailed studies. Documentary, quantitative evidence should be obtained wherever available. However, it is recognised that these are likely to be largely qualitative studies making extensive

use of semi-structured interviews with key informants. Given funding and time limitations, the studies will not undertake significant original data gathering.

Country studies: The precise range of programmes will vary from country to country. Fieldwork in each country will be undertaken in a two-week visit by two international and one national consultant, plus an additional national consultant in countries where both HIV/AIDS and tropical disease programmes are examined. Undertaking the work in a two-week visit will require effective pre-visit preparation and the prior development of base documentation on the country context and the individual PPP/programmes. The country studies should adopt a layered approach to evaluation, covering the country context and the disease control policy before assessing the individual partnership programmes. Fieldwork will include interviews about each programme at national, regional (where appropriate), district and health facility levels. Criteria for selection of districts should include:

- Active implementation of those PPP programmes being studied, ensuring that each programme is visited in at least one district. HIV/AIDS programmes should be examined in the capital and at least one contrasting district.
- Regional and socio-economic representation.
- Accessibility, within the timescale of the study.

Information collection:

Appendix B provides suggested information collection tools for:

- The individual drug donation/discount programme (e.g. Merck's Mectizan Donation Programme.
- The broader PPP partnership (e.g. the Global Alliance to Eliminate Lymphatic Filariasis, GAELF).

The national disease programme: Appendix C specifies minimum data requirements, with possible sources, for the country context, the national disease control policy and the specific PPP programme.

Key informants and issues at country level: Fieldwork should include interviews about each relevant programme at national, regional (where appropriate), district and health facility/community levels. Appendix D suggests likely informants, Appendix E suggests possible national level questions for tropical disease programmes, Appendix F suggests possible national level questions for HIV/AIDS programmes, and Appendix G suggests possible district level questions. These generic questions will need to be tailored to the specific context of the countries selected. (Appendices not included.)

ANNEX 2

People interviewed

Christopher Simoonga, Assistant Director Management Information (National Epidemiologist) MOH
Ben Chirwa, Director General, CBOH
Velephi Mtonga, Director Clinical Services, CBOH
Miriam Chipima, adolescent and reproductive health specialist, CBOH
E. Sinyinza, Director Public Health and Research, CBOH
Naawa Sipilanyambe, malaria specialist, National Malaria Control Programme, CBOH
R. Andala, pharmacy specialist, CBOH

Rosemary Musonda, Acting Director General, NAC
Alex Simwanza, Director Programmes, NAC

Ron Mutati Kampamba, Chief Executive Officer, MSL
Rose Sichalwe, MSL
David Simonga, MSL
Gladys Sinyambe, MSL
Frank Kamwale, Pharmacy and Poisons Board
Chifumbe Chintu, Chair National Formulary Committee, UTH
Chipepo Kankasa, Clinical Head of the Paediatric Department, UTH
Peter Mwaba, Head of Department of Internal Medicine, UTH

Simon Mphuka, Director of Programmes, CHAZ
Tryson Ngalande, leprosy focal point, CHAZ
Chishiba Chibuta, pharmacy specialist, CHAZ

Tony Daly, DFID
Stella Anyangwe, WHO Representative, Zambia
Eddie Limbambala, medical officer, Disease Prevention and Control, WHO, Zambia
Kanyanta Sunkutu, country team adviser (HIV/AIDS), WHO, Zambia

Dorothy Kasonde, Mutti Medical Clinic
Oliver Hazemba, Management Sciences for Health
Deidre Allison, Director, Zambia HIV/AIDS Business Sector Project
Elizabeth Mwila, Home-based care project, Family Health Trust

Chibombo District

James Simeja, Manager Administration, DHMT
Phumulo Nakando, Manager Planning and Development, DHMT
Mike Lungo, HIV Focal Person, DHMT
Iris Moonga, Pharmacist, Litete District Hospital

Lusaka Urban District

Moses Sinkala, District Director
Mpundu Makasa, Manager Planning and Development
Maxwell Kasonde, pharmacy coordinator
Graham Samungole, TB/leprosy focal point
Maureen Chiviema, in charge, Kalingalinga Clinic, Lusaka Urban
Sylvia Simanya, midwife, Kalingalinga Clinic, Lusaka Urban
Diana Mukandi, pharmacy manager, Kalingalinga Clinic, Lusaka Urban
Anne Katuta, in charge, Chelston Clinic, Lusaka Urban
Dora Luhanga, in charge, Chelston PMTCT Plus project
Chebesa Wamulume, doctor, Chelston PMTCT Plus project
Edwin Kaoma, pharmacy technician, Chelston PMTCT Plus project

Mpika District

Daniel Zulu, Acting Senior Nursing Officer, Mpika District Hospital
Kennedy Simukanga, pharmacy technologist, Mpika District Hospital
Joseph Nkwenda, TB/leprosy focal point, Mpika District Hospital

Dorothy Siyambelela, psychological counsellor/ radiographer, Mpika District Hospital
Pauline Borsboom, Executive Director, Chilonga Mission Hospital
Claudius Makasa, pharmacy technologist, Chilonga Mission Hospital
Fewdays Chibuye, HIV/AIDS focal point, Chilonga Mission Hospital
Cornelius Mutalo, family health nurse i/c OPD, Chilonga Mission Hospital
Bowas Lukama, enrolled nurse, Kapa Rural Health Centre

Ndola District

Victor Mwanakasale, Principal Scientific Officer, Tropical Diseases Research Centre
Victor Chalwe, Acting Head, Clinical Services, Tropical Diseases Research Centre
Benedict Tembo, Pharmaceutical Manager, Ndola Central Hospital
Billy Mweetwa, pharmacist, Ndola Central Hospital
Robert Hantenda, Manager Administration and Human Resources, DHMT
Watson Mulwa, pharmacy technologist, DHMT
Paul Dondolo, environmental health expert, DHMT
Annie Banda, programme officer, Linkages PMTCT Project
Betinas Mwanza, PMTCT Coordinator, New Masala Clinic
Patrick Mubiana, environmental health specialist, Ndola Provincial Health Office

ANNEX 3

National Malaria Prevention and Control Programme

Background

At independence in 1964, Zambia inherited a health system that was efficient but divided along urban-rural and racial lines. There were few health facilities for the majority of the population and therefore no equity of access to health. Although malaria was the main health problem, cases were largely confined to rural areas with most urban centres and larger towns being malaria-free. Rigorous enforcement of and adherence to public health measures contributed to the decline of malaria in urban areas.

Political commitment and progress in Roll Back Malaria

Over the past few years, the Government of the Republic of Zambia (GRZ) has demonstrated its commitment to fight the growing malaria problem at the highest possible level. The President signed the WHO African Initiative on Malaria (AIM) during the meeting of the OAU heads of states and governments in Zimbabwe in 1997. When AIM was incorporated into the Roll Back Malaria (RBM) process, the President expressed the country's continuing commitment to fight malaria in a letter to the Director-General of WHO.

In 1999, the President of the Republic attended the WHO-sponsored pan-African RBM meeting in Abuja and signed the Abuja Declaration, committing Zambia to Roll Back Malaria. In 2000, the President formed a National Malaria Task Force, chaired by the Deputy Minister of Health and attended by the line ministries, and a National Malaria Secretariat, headed by the National Malaria Control Centre (NMCC).

Since that time, the National Secretariat, led by NMCC, has completed the RBM inception process involving the national level and all 72 districts in Zambia. Concrete results to date have included the completion of a Situation Analysis, National Malaria Strategy, district-level situation analyses and strategies, the expansion of the National Working Group to include NGOs, churches, key international agencies and the private sector, advocacy for elimination of taxes and tariffs on insecticide-treated nets (ITNs), netting material and insecticide, and the formation of a Malaria Drug Policy Technical Advisory Group which has made recommendations to the MOH/CBOH on changes in first-line and second-line drugs.

The National Malaria and Prevention Control Programme

The programme is coordinated by the NMCC, which is one of the secretariats of the Global Fund CCM. Other implementing agencies include the public sector, the private sector and NGOs. The objective of the programme is to reduce malaria mortality and morbidity in the country, by increasing access to effective treatment, in the light of chloroquine resistance, and by increasing the distribution of ITNs. The programme benefits the whole population, but is targeted especially at those most vulnerable to malaria such as pregnant women and children under the age of five, and those living in rural communities difficult to reach by the road transport network. Programme strategies include: case management; scaling up access to and distribution of ITNs; improving technical support for vector control; and laboratory diagnostic capacity and drug monitoring information system.

Antimalarial drugs

Chloroquine (CQ) was the first-line antimalarial drug in Zambia until November 2001, when government made a "brave and drastic" policy change and moved to the combination therapy artemether-lumefantrine (Coartem®). CQ was immediately withdrawn from all health facilities and sulphadoxine-pyrimethamine (SP) was used in the

interim as a first-line drug for treating uncomplicated malaria. The policy change was a result of acknowledgement of the magnitude of the burden of malaria in the country and the high resistance to CQ identified in resistance studies. The government went ahead with this policy change despite resistance from Zambia's traditional donor partners. SP is used for intermittent preventive treatment (IPT) in pregnant women and for treatment of pregnant women and children under two years or below 10 kg since Coartem® is contra-indicated in these two population groups. Quinine continues to be the drug of choice for management of complicated and severe malaria.

Drugs for public health facilities are requested by districts and purchased centrally through the Medical Stores (MSL). A laboratory facility for quality control checks on all drugs procured by or through the MSL is used to verify the quality of drugs bought. Drugs for health centres and hospitals are delivered as pre-packed essential drug kits with prescribed types and quantities of drugs. These drugs are bought on the central level with funds from government and donors.

At community level, community health workers (CHWs) – trained volunteers with responsibility for health promotion, prevention, case detection and case management – dispense basic drugs to people who are sick. There are special drug kits requested by health centres and sent to districts for CHWs. These kits were meant to enable CHWs to provide prompt treatment in the community.

Proposed social marketing of Coartem® in Zambia

Studies in Zambia have found that half of patients and caretakers seek treatment for malaria through the private sector (RPM Plus, 2003). To ensure adequate access to Coartem® by those who need it, it has been proposed that Coartem® be made available through selected outlets in the private sector, with technical support to the CBOH from the Rational Pharmaceutical Management Plus Programme (RPM Plus). Currently Coartem® is available only through the public sector in 28 of Zambia's 72 districts. Novartis markets the same product under the brand name Riamet, which is available for sale through the private sector at a much higher unsubsidised price of US$12 per adult treatment course. (The subsidised cost of Coartem® available in the public sector through the PPP is US$ 2.40.)

The proposal for social marketing of Coartem® has been agreed in principle between the GRZ, WHO and Novartis. It is envisaged that this programme will begin in three districts in October 2004 and will scale up gradually over two years. The proposal was that NMCC, in its capacity as a Government Agent, would enter into an agreement with Society for Family Health (SFH), a social marketing NGO established by the Pharmaceutical Society of Zambia (PSZ) and Population Services International (PSI), which would store, distribute and manage the distribution of Coartem® through selected retail pharmacies or shops in districts where Coartem® will be distributed in the public sector. However, since SFH will only undertake this responsibility if it is able to over-brand the product (in order to differentiate any stock that is leaked from the public sector from that marketed through SFH) but Novartis and WHO are unlikely to agree to over-branding, it has been proposed that PSZ be contracted to manage and distribute the product. PSZ, an NGO founded and managed by the pharmacy profession, has an institutional collaboration agreement with CBOH to promote rational use of drugs, and provides technical assistance in formulary management, TB, HIV/AIDS and malaria and in development of pharmacy education.

The government will use GFATM funds to finance the procurement of Coartem® from Novartis through WHO. The cost of storage, distribution and contracting will be covered by the sale price of the product to private sector retail outlets. An agreed amount of Coartem® will be apportioned and transferred to a PSZ warehouse. This will avoid the costs that would be incurred if stock were obtained from MSL, which charges a management fee for every commodity.

PSZ will enter into an agreement with a selected number of pharmacies and retail outlets in the three districts. These outlets will be chosen on the basis of location, presence of a full-time pharmacist and ability to implement, including keeping updated records. In four additional districts where there are no formal pharmacies, DHMTs will assist in identifying outlets of good repute to participate in the pilot phase. Implementation will be extended to other districts as directed by the NMCC.

The contract with private sector outlets will be guided by the NMCC, in line with existing government policies and legislation. PSZ will sell Coartem® to the outlets at a price agreed between the NMCC and PSZ. In addition to a 3% management fee charged by WHO, MSL and PSZ will add handling charges. Pharmacies will be allowed to charge a small dispensing fee to patients or caretakers, to provide an incentive and to prevent significant leakage from the public to the private sector. As provided by WHO for recognised NGOs working with the permission of CBOH using the reimbursement procurement systems, PSZ will use funds raised from dispensing fees for further procurement of Coartem®.

ANNEX 4

Evolution of malaria and Coartem® policy and malaria treatment guidelines

	Globally	Zambia
1995		National Malaria Secretariat established
1998	Artemether–lumefantrine first registered in Switzerland and UK/EU	Establishment of National Malaria Control Centre
Oct 1998	Roll Back Malaria (RBM) launched	
1999		President commits Zambia to RBM
1999	1st application for inclusion of artemether–lumefantrine on WHO Model List of Essential Drugs (EDL); decision deferred pending resolution of some issues; artesunate added to WHO EDL	
2000		National Malaria Task Force established by President
March 2000		National Malaria Situation Analysis completed and reviewed to develop the Zambian RBM Strategic Plan
April 2000	Abuja summit sets goals for Roll Back Malaria	Zambia signs the Abuja Declaration
Nov 2000	Novartis agree to make Coartem® available to WHO at "cost price"	
2001	Memorandum of understanding between Novartis and RBM on use of Coartem® WHO issues guidelines for use of artemether–lumefantrine	Zambian Strategic Plan for Rolling Back Malaria finalised
Feb 2001	South Africa/KwaZulu Natal adopts artemether–lumefantrine as 1st line treatment	
2002	Patient blister packaging developed and tested	Zambian policy change to Coartem® adopted
Feb 2002	Public sector prices established based on six-dose regimen and patient blister packaging	
April 2002	Artemether–lumefantrine incorporated into the WHO EDL	Zambia submits 1st round Global Fund Proposal with malaria component to procure artemisinin combination therapy
April 2003		MSF Holland provides Coartem® to seven pilot districts
Aug 2003		WHO procures Coartem® for seven districts
8 Sept. 2003		Global Fund funding guarantees payment for Coartem® for Zambia and order placed with WHO for U$ 2,805,049
Nov 2003		Delivery of Coartem®
2004		Coartem® included in the Zambia Essential Drug List

Treatment guidelines for Zambia according to the 2002 policy change

Adult and children >10kg 1st line	Artemether–lumefantrine
Children <10kg	Sulphadoxine- pyrimethamine (SP)
2nd line	Quinine
Severe malaria: 1st line	Quinine
Pregnancy 1st line: 1st trimester	Quinine
Pregnancy 1st line: 2nd/3rd trimester	SP (artemether–lumefantrine under supervision)
Pregnancy 2nd line	Quinine after failure of SP
Intermittent preventive treatment in 2nd and 3rd trimesters of pregnancy	SP

Dosing, pack sizes and procurement prices (WHO/Novartis)
November 2001 to February 2002

Coartem® [artemether–lumefantrine tablets 20/120mg]		
Child 10–14 kg	1 x 6 (6)	US$ 0.90*
Child 15–24 kg	2 x 6 (12)	US$ 1.40*
Child 25–34 kg	3 x 6 (18)	US$ 1.90*
Adult >35kg	4 x 6 (24)	US$ 2.40*
Commercial packs	24 tablet blisters	Public sector: US$ 2.35; Private sector: US$ 12

Price includes "new" packaging and dispensers – valued at a unit cost of US$0.40 (all variants)
* Agreed February 2002

ANNEX 5

Evolution of HIV drug-related policy and programmes

Background to the HIV/AIDS epidemic

The first case of AIDS was reported in Zambia in 1984. By 2002, prevalence at selected antenatal sentinel surveillance sites had reached 25.6% in urban areas and 11.3% in rural areas. The 2001–2002 Zambia Demographic and Health Survey (ZDHS) found that 18% of women and 13% of men aged 15-49 years were HIV positive; almost 50% of women in this age group living in urban areas are infected. Rates vary significantly by region, ranging from a low of 8% in the Northern province to a high of 22% in Lusaka (CBOH 2002).

The 2001–2002 ZDHS found that the adult mortality rate had risen by more than 15% since the previous survey in 1996–1997. More than half of 15-year-olds can now expect to die from AIDS, most before the age of 35. There is little evidence of a decline in infection rates amongst younger age groups. Women in particular are more vulnerable and infection rates rise rapidly with age. Young women aged 15–19 years are more than five times as likely to be infected as young men in this age group (CBOH 2002).

These rates are also reflected in the high incidence of mother-to-child transmission, with an estimated 30,000–40,000 infants infected each year. According to the 1998 Zambian Living Conditions Monitoring Survey, there were 533,000 orphaned children, of whom 6% were living on the streets. Families and grandparents are struggling to provide these children with the care, resources and supervision they need. There are also increasing numbers of child-headed households.

The Zambia Poverty Reduction Strategy Paper (PRSP) identifies HIV/AIDS as the country's most important cross-cutting development issue and notes that AIDS has reversed the social and economic gains made since independence. HIV/AIDS is specific budget line within the PRSP with an allocation of US$ 94.6 million (nearly 8% of the total) (Lake 2004). The goals for HIV/AIDS within the PRSP include measures to reduce new infections, promote positive and healthy living among asymptomatic PHA, improve the quality of life of those with AIDS, improve the quality of life of orphans, and strengthen monitoring, evaluation and surveillance systems.

The impact of HIV/AIDS on the health sector is both direct and indirect. The direct impact includes increased costs associated with treating OIs and caring for those dying from AIDS. HIV-related health care costs are estimated to have increased from US$ 3.4 million in 1989 to US$ 18.3 million in the late 1990s (GFATM Round 1 Proposal). The burden on hospitals is especially high with around 70% of beds reportedly occupied by patients with AIDS-related conditions. The indirect impact includes attrition of health sector personnel through HIV/AIDS-related illness and death.

HIV/AIDS policy context in Zambia

Until recently, political support for efforts to tackle HIV/AIDS in Zambia was relatively weak. Prevention interventions were constrained by limited resources and high levels of social stigma. Mechanisms for accountability and collaboration between key government sectors to support a multisectoral approach to HIV/AIDS were inadequate (MOH 2004).

Since 2000, there has been greater political commitment to health and HIV/AIDS: annual expenditure in the health sector has steadily increased and HIV/AIDS receives priority in health plans. The 2001-2005 National Health Strategic Plan outlined a new HIV/AIDS strategy, incorporating mobilisation of national leadership, a multisectoral approach and policy, development of national guidelines, integration of health sector activities in existing systems to strengthen coordination, tracking of social and cultural barriers to implementation, strengthening prevention and care of OIs as well as home-based and orphan care, and

enhanced mobilisation of financial resources. The policy environment has also changed considerably since 2000, with the advent of new external funding sources (GFATM, World Bank MAP 2, and PEPFAR) and, in 2004, the government developed a policy and operational guidelines to scale up ART in Zambia.

A Committee of Ministers on HIV/AIDS/STD/TB heads the administrative structure governing development and implementation of HIV/AIDS policy. In 2000, this committee established the National HIV/AIDS/STD/TB Council (NAC) and Secretariat to lead policy development and a number of specialised Technical Working Groups (TWGs). In 2000, the NAC published the National AIDS Policy and HIV/AIDS/STD/TB Strategic Plan 2001–2003.

The NAC has since published a second Strategic Plan and budget for 2002–2005. In 2002, a National Action Plan for implementation of AIDS-related activities was adopted. TWGs cover: information, education and communication; PMTCT; treatment, care and support; VCT; orphans and vulnerable children; monitoring and evaluation; HIV/AIDS at the workplace.

To implement the Strategic Plan, focal points were identified in each Ministry and at provincial and district levels to coordinate HIV/AIDS programmes and build capacity for implementation. Within the CBOH, an HIV/AIDS Committee was established in 2003. The private sector and NGOs have also been mobilised and there is a Country Coordinating Mechanism to oversee GFATM applications and implementation.

Zambia faces many constraints in scaling up its HIV/AIDS response. A critical issue is the impact of the epidemic on the demand for health care and the supply of health workers. The health sector's HIV/AIDS plan was criticised in the 2004 Health Sector Mid-Term Review for lack of a clear strategy to address health worker attrition, including the costs and benefits of providing treatment to these workers. Another critical issue is lack of clear division of responsibility for HIV/AIDS policy development and implementation, and poor communication, between the NAC and the CBOH.

Developments in policy and programming

Prevention of HIV

Under the 2002–2005 Strategic Plan, a range of public and private sector initiatives has been established to prevent the spread of HIV. These include initiatives by faith-based organisations, missions and workplaces, social marketing of condoms, programmes targeting youth and high-risk groups such as sex workers, truckers, defence forces, prisoners and refugees.

Prevention of mother-to-child transmission

Efforts to prevent mother-to-child transmission started in 1999 with a pilot programme funded by UNICEF and a number of NGOs. In 2002, the CBOH began a programme to scale up PMTCT services and, in 2003, published a Strategic Framework for the Expansion of PMTCT Services 2003–2005. The goals of the Strategic Framework are to expand PMTCT to all 1,284 MCH facilities in 72 districts by 2005, provide VCT to 70% of women at the first ANC visit, provide ARV monotherapy (zidovudine or nevirapine) to positive women and increase the proportion of women who exclusively breastfeed for six months to 70%. These goals will be achieved through primary prevention both of HIV and pregnancy, PMTCT among HIV-positive mothers, expanding community care and support, and establishing referrals to other relevant programmes.

Table 9. Women benefiting from the PMTCT programme, September 2002

Intervention	Working group sites (May 2000–Sept 2002) Number (%)	Call to action sites (Aug 2001–Oct 2002) Number (%)
First ANC attendants	30,593	10,668
Pre-test counselled	6,742 (22.1)	8,400 (79.0)
Tested	4,339 (14.2)	7,860 (73.7)
HIV-infected (from site prevalence data)	7,556 (24.7)	2,346 (22.0)
HIV-infected mothers delivered	522	555
Deliveries received ARVs	768 (10.2)	547 (23.3)

Source: CBOH 2003b

Demand for PMTCT services has been estimated based on existing pilot sites (Table 9). These figures have been used to plan service expansion and estimate drug and test kit supply needs. Ongoing monitoring and evaluation at pilot and scale-up sites will be used to adjust demand estimates.

Functional development of PMTCT sites at MCH clinics will be achieved through a system of site preparedness accreditation that includes training of health workers, allocation of private space for counselling, logistical arrangements for rapid testing, management of supplies, supervision, monitoring and evaluation, a district technical working group, a site focal point, patient management flow and community engagement activities.

The programme will be scaled up in stages:

- In Stage 1, advocacy and resource mobilisation efforts will be intensified along with policy development, coordination by the CBOH and capacity development for managers and clinical staff.
- In Stage 2, PMTCT will be integrated into all district plans around training of health providers, strengthening and integration of drug supply systems, coordination with relevant health centre and community initiatives, and development of counselling skills. In addition, monitoring and supervision of the programme will be integrated with district activities.

The three-phase expansion plan aims to cover 100% of MCH facilities by the end of 2005:

A PMTCT protocol and guidelines were also published in 2003, covering care for mothers, infants and health workers, and monitoring and evaluation. Drugs to be provided to mothers and infants are: AZT 300mg tablets daily from 34 weeks and 300mg three-hourly during delivery or nevirapine 200mg for the mother at the onset of labour and a single dose 0.2ml/kg syrup for the baby within 72 hours of birth.

The PMTCT programme will remain the responsibility of the CBOH and will be reviewed by the Health Information System Unit and the reproductive health specialist using routine monitoring systems and annual programme review. Formal evaluations will be conducted in 2004 and 2005. In addition, the PMTCT TWG under the NAC acts as an advisory body to the CBOH and is responsible for developing policy, coordinating future interventions and fostering local, national and international networks on PMTCT in collaboration with the CBOH. In 2004, it is likely that the TWG will recommend a change in policy from monotherapy for PMTCT to dual or triple therapy. Other critical policy issues to be addressed include relatively low attendance at health facilities for delivery (53% compared to 98% attendance for ANC), low demand for VCT among pregnant women, post-natal care and infant feeding advice to mothers, and establishing better links with other reproductive and child health programmes.

Treatment of opportunistic infections

Guidelines for the treatment of OIs were developed in 2001. These have since been revised and are currently being finalised. The revised guidelines were not available for review, so it was not possible for this study to assess their content with respect to treatment of cryptococcal meningitis and oesophageal candidiasis. A training package on the management of OIs has been developed and is also in the process of being finalised. While plans to scale up ART discuss the importance of OI treatment, the increased emphasis on ARVs may shift attention away from management of drugs required to treat OIs.

Antiretroviral therapy

The Zambian government did not participate in the AAI. Until 2002, when the government took the decision to make ART available in the public

Table 10. PMTCT expansion targets by province, district and health facility

Year	Province	Districts (% covered)	Health facilities (% in each district)	Partnering agencies/ NGOs	Cumulative % of districts covered
2003	All	20%	40%	All partners	20%
2004	All	40%	40% new 80% old	All partners	60%
2005	All	40%	100%	All partners	100%

Source: CBOH 2003b

sector, treatment and care initiatives focused on home-based care, human rights promotion and access to treatment for OIs, ARVs were only available through the private sector and an estimated 2,000 people were paying privately for treatment.

In 2002, the government allocated US$ 3 million for the purchase of ARV drugs for 10,000 PHA. Two pilot sites were established at Lusaka's University Teaching Hospital (UTH) and Ndola Central Hospital. The programme has since expanded to nine provincial centres and, as of March 2004, nearly 3,000 PHA had accessed the government ART programme with all nine provincial sites and Lusaka UTH providing some services. The majority of these are using Triomune, a relatively cheap generic combination therapy procured from Cipla in India.

In 2003, Zambia embraced the WHO 3-by-5 ART initiative, under which it has increased its target for ART access from 10,000 to 100,000 by the end of 2005, when ART should be available in all 72 districts. The target of 100,000 will be achieved through public, NGO and private sector facilities, with the government providing training, capacity building and support to all sectors. There will be a certification process and accredited facilities will have access to government-procured drugs (primarily generic ARVs) under the reduced prices available to the public sector.

The total cost of the programme is estimated at US$ 35.68 million, based on a model by Abt Associates, in which the cost per patient per year is US$ 488.02 (including ARVs and drugs for OIs, laboratory tests, capital items and training). In 2003, the government allocated US$ 3 million from the national budget to purchase ARV drugs. A further allocation is anticipated for 2004, but the current fiscal deficit is likely to restrict the amount available from the national budget. Other sources of funds to meet the financing gap of approximately US$ 30 million include: HIPC (for which Zambia may soon qualify); GFATM (US$ 2 million earmarked for ARV drugs for 2004 under Round 1 and a proposal submitted under Round 4); World Bank (has awarded funds under MAP2 for PMTCT Plus); PEPFAR (USAID is currently supporting PMTCT); and other cooperating partners such as JICA which supports infrastructure development at UTH.

ANNEX 6

PPP information summaries

WHO/Novartis Public Purchase Agreement (Coartem®, malaria)

Country programme background/ assessment of disease in national/district health strategy and plan

Zambia signed the WHO African Initiative on Malaria (AIM) during the meeting of the OAU heads of states and governments in Zimbabwe in 1997. In 1999, the President attended the WHO-sponsored pan-African RBM meeting in Abuja and signed the Abuja Declaration, committing Zambia to Roll Back Malaria. In 2000, the President of the Republic formed a National Malaria Task Force, chaired by the Deputy Minister of Health and attended by the line ministries, and a National Malaria Secretariat, heading the National Malaria Control Centre (one of the secretariats to the GFATM Country Co-ordinating Mechanism). Zambia adopted a new policy on use of artemisinin-combination therapy (ACTs) in November 2001. The policy change to adopt the ACT artemether-lumefantrine (Coartem®) was made in February 2002. This radical policy change at the highest level in the Ministry of Health was a result of acknowledgement of the magnitude of malaria and the increasing resistance to chloroquine, which had tripled in the past 20 years and now ranges from 10-69% across the country.

Programme objectives and strategy in Zambia:
To provide effective and free treatment through public (and authorised private providers) for malaria, starting with seven pilot districts, with full coverage by 2004

Conditionalities:

- countries have to register the drug
- the country has to request the product from WHO
- the drug must be needed and in national treatment guidelines
- a distribution system must be in place
- the cost to the client must be reasonable
- previous procurements must be accounted for
- If diversion from public to private sector happens, the country gets a warning. If a diversion happens a second time, the product may be pulled and no further orders may be placed
- Product may be sold and/or distributed in the private sector, but price must not be "unduly raised."

Nature of partnership (range of partners; partner motivation and objectives)
National Malaria Control Programme, Provincial Health Management Teams, District Health Management Teams, NGOs, Tropical Disease Research Program, WHO

Programme start date, stage of development, future plans
Start date: policy change: February 2002; first supply: February 2003; first distribution: April 2003

Stage of development: the initial seven pilot districts have been scaled up to 28 districts

1.94 million treatment courses received to date with Global Fund money

Future plans: to scale up to all 72 districts by end 2004

Governance arrangements: Zambia met the conditionalities set for supply by WHO under the WHO/Novartis agreement (see above)

Secretariat/manager and personnel: National Malaria Control Programme: Dr Sipilanyambe Naawa. At local level: integrated into normal disease and drug management functions

Budget and actual spend: Sources of funds: funded under grants for malaria from Global Fund for AIDS TB and Malaria

Presentation of programme to beneficiaries: The policy change to Coartem® received some press

coverage, however, most health workers interviewed were not aware of the discount arrangement. Community awareness and demand for the drug as an effective treatment was reflected in reported increases in patient numbers. A local name given to Coartem® is iwatemwa ("we are happy")

Mode of operations: Health centres send monthly returns to the district office where information is collated and sent to the National Malaria Control Programme. Monthly forecasts made by the NMCP to WHO. Initially "push" system, based on CQ/SP consumption and malaria incidence, was used for drug allocation. Subsequent drug allocation was on a "pull" system, which is based on Coartem® utilization/ consumption. Also a new national programme on pharmacovigilance especially for inadvertent use in pregnant women and children under 10 kg, for which a report is mandatory.

Current geographical and epidemiological coverage (e.g. current scale of coverage compared with planned coverage; coverage by socio-economic status, gender, age, rural/urban location): No data reported. Coverage in 28 of 72 districts – both urban and rural

Overall performance against targets to date: Coartem® is targeted at public sector patients in all 28 pilot districts as per strategic plan. NMCP plans to scale up to all 72 districts by 2004

Sustainability measures: Grants from Global Fund for AIDS TB and malaria likely to sustain procurements for at least the next three to five years

Issues

Value-added: Coartem® is an effective drug for the treatment of malaria where resistance is a major concern and would be difficult for Zambia to access financially in the absence of steep price discounts and GFATM grants

Criticisms: Purchase solely dependent on disbursement of funds from grants from GFATM, which has to date led to a sporadic supply; some reports that traditional donors to Zambia health sector may have concerns about the relatively high cost of sustaining the programme

Comments: The biggest challenge for Coartem® is to ensure that drug supply is not interrupted at either procurement or distribution stages for financial or logistical reasons, especially once the programme scales up from the 28 pilot districts to all 72 districts in the country.

WHO/Novartis Public Purchase Agreement (MDT, leprosy)

Country programme background/ assessment of disease in national/district health strategy and plan

National elimination was achieved in 1999 although patches of disease endemicity remain in the country. The leprosy elimination situation in Zambia at the end of December 2000, established by reviewing data forwarded to the National Leprosy Control Unit quarter by quarter, district by district, was as follows; the national registered prevalence of leprosy was 686 (555MB, 131PB). This gave a national prevalence rate of 0.68 per 10,000 population. The proportion of children among reported new cases in 2000 was 4.8%. However, in Western and Luapula provinces, prevalence rates of 1.3/10,000 population (Western province) and 3.3/10,000 population (Luapula province) have been noted. In 2003, 314 cases of leprosy were detected. The current prevalence is 247, far below the elimination target of 1/10,000 population.

Multi Drug Therapy (MDT) was introduced in a few pilot districts in Zambia in 1986, when leprosy control activities were initiated in the country, and 100% MDT coverage was achieved in 1991. Before receiving MDT under WHO-Novartis programme in 1999, from 1997-1999, drugs were provided by WHO using the drug fund financed by the Nippon Foundation.

The Central Board of Health (CBOH) in collaboration with the Churches Health Association of Zambia (CHAZ) operates the National Leprosy Control Programme in Zambia. The CBOH and CHAZ have had a long-established national leprosy elimination campaign.

Programme objectives and strategy in Zambia:

The national programme objectives are to maintain (and further reduce) leprosy at elimination levels and to reach the elimination target (<1 patient/ 10,000 population) at subnational level in areas where prevalence remains higher.

Conditionalities:

- Norvatis has to register the drug in every country and the drugs should meet quality standards.
- Treatment should be free to patient.

Nature of partnership (range of partners; partner motivation and objectives)
Ministry of Health, Central Board of Health, provincial health management teams, district health management teams, Churches Health Association of Zambia, The Leprosy Mission International, Netherlands Leprosy Relief International, Novartis, NWHO

Programme start date, stage of development, future plans:
Zambia entered the Novartis-WHO PPP in 1999

Stage of development: 100% MDT coverage of leprosy patients was achieved in 1991; national elimination was achieved in 1999

Future plans: To continue with leprosy elimination campaigns until the WHO elimination target of <1/10,0000 population is reached at subnational level in endemic areas in the country.

Governance arrangements: Zambia met the conditionalities set for supply by WHO under the WHO/Novartis agreement (see above)

Secretariat/Manager:
National Leprosy Control Programme CBOH TB/Leprosy specialist

Dedicated personnel:
- national: CBOH TB/Leprosy specialist and CHAZ leprosy focal point,
- local: integrated into normal disease and drug management functions

Budget and actual spent; sources of funds: Government contribution unquantified; TLMI supports CHAZ in a five-year project from 2001-2005. The total budget for 2002 was US$ 100,000; Netherlands Leprosy Relief International recently signed an agreement with the CBOH to fund the CHAZ Leprosy Control Programme.

Mode of operations: Health centres (HCs) make monthly reports to district health management teams. Districts send monthly consumption forms to TB/Leprosy secialist at CBOH. Drug requisitions from districts processed quarterly by pharmacy department. Drug orders distributed quarterly from Medical Stores Ltd to districts with drug kits. Drugs distributed to HCs quarterly with drug kits.

Current geographical and epidemiological coverage (e.g. current scale of coverage compared with planned coverage; coverage by socio-economic status, gender, age, rural/urban location): 100% MDT coverage of leprosy patients was achieved in 1991.

Overall performance against targets to date: MDT is targeted at all leprosy patients in districts where leprosy is endemic.

Sustainability measures: The close working relationship between the CBOH and the CHAZ Leprosy Control Programmes, the latter with the support of TLMI and NLRI, will ensure sustainability of the programme.

Linkages with other programmes: The Leprosy Control Programme is integrated with the TB Control Programme and is managed by the TB/Leprosy specialist who is based at the CBOH.

Comments: The biggest challenge to the CBOH and CHAZ is to ensure a constant supply of MDT to all health facilities in leprosy-endemic districts in order to secure elimination of leprosy at subnational level.

Boehringer Ingelheim Viramune® Donation Programme (Preventing mother-to-child transmission of HIV)

Country programme background/ assessment of disease in national/district health strategy and plan

Efforts to prevent mother-to-child transmission started in 1999 with a pilot programme funded by UNICEF and a range of NGOs. In 2002, the CBOH began a programme to scale up these services to all 1,284 sites nationally and, in 2003, published a Strategic Framework for the Expansion of PMTCT Services and a protocol and guidelines. Critical policy issues include relatively low attendance at health facilities for delivery (53%, compared to 98% attendance for antenatal care), low demand for voluntary counselling and testing (VCT) among pregnant women, and what to recommend to mothers for post-natal care and feeding options. Furthermore, establishing better links with other key reproductive and child health programmes is a priority.

Programme objectives and strategy in Zambia
Within the Strategic Framework, current programme goals include expansion to all MCH facilities in 72 districts by 2005, to provide VCT to 70% of women at first ANC visit, to ensure that those positive receive ARV monotherapy (zidovudine or nevirapine), to increase level of ex-

clusive breastfeeding for six months to 70%, to expand community care and support activities, and to establish referrals to other relevant programmes. These goals will be achieved through primary prevention of both HIV and pregnancy, preventing mother-to-child transmission among HIV-positive mothers, and care and support of mothers and children through a broader programme. This programme is dealt with in more detail below.

Conditionalities
Applications are screened by Axios and a panel of experts on a range of issues including health information and inventory management.

Nature of partnership (range of partners; partner motivation and objectives)
CBOH, NAC, Centre for Infectious Disease Research (CIDRZ – Columbia University), AED-Linkages, US Agency for International Development (USAID), UNICEF

Programme start date, stage of development, future plans
Start date: During 2001 from Boehringer Ingelheim direct to several pilot projects.

After May 2003 from Axios to centralised programme at CBOH.

Stage of development:
By March 2004 there were 75 pilot PMTCT sites in 11 districts – mostly in partnership with pilot sites.

During May-October 2003, 1,968 adult doses and 1,434 baby doses were prescribed nationally.

Future plans
Expansion targets by province, district and health facility

Year	Province	Districts (% covered)	Health facilities (% in each district)	Partnering agencies/ NGOs	Cumulative % of districts covered
2003	All	20%	40%	All partners	20%
2004	All	40%	40% new 80% old	All partners	60%
2005	All	40%	100%	All partners	100%

Governance arrangements:
Directed by the reproductive health specialist in the CBOH. No contact between CBOH and Boehringer Ingelheim. All communication handled by Axios.

Secretariat/manager: Reproductive health specialist, CBOH

Dedicated personnel
- national: No dedicated personnel. Day-to-day management at CBOH through reproductive health specialist
- local: None. Day-to-day management currently with midwives on maternity wards.

Budget and actual spend; sources of funds
Without money or time limits as long as conditionalities adhered to and for enrolled patients

Mode of operations
The MoH places orders through Axios, the supplies are delivered to Medical Stores Limited.

Utilisation data for all participating facilities is required before an order will be accepted. In practice, obtaining utilisation data for all facilities at the time when an order needs to be made at the national level (to avoid stock outs) is proving to be problematic – there are concerns that when the programme is scaled up to all districts that achieving utilisation information for all the facilities before an order can be made will not be feasible. The CBOH is receiving support from international NGOs in collating necessary data.

Current geographical and epidemiological coverage (e.g. current scale of coverage compared with planned coverage; coverage by socio-economic status, gender, age, rural/urban location)

Overall performance against targets to date
May–October 2003 in pilot districts:

20% ANC receiving VCT (target 70% in all districts by 2005).

38% HIV positive mothers and 28% babies receiving Viramune® (target 75% by 2005).

Sustainability measures
As long as the conditionalities are met, the donation is limited to five years. Shifts in PMTCT drug guidelines and new evidence on resistance to single dose monotherapy with nevirapine may render the donation unusable.

Linkages with other programmes
Some links with ART through PMTCT plus initiatives – but these are mainly through international NGO projects.

Issues
Value-added: While the PMTCT programme would probably be functioning even in the absence

of this donation programme (because of the number of external partners interested), procuring generic nevirapine for PMTCT was reported to be more costly than managing the donation programme. Axios was reported to have been supportive to the programme manager in navigating institutional constraints and estimating demand.

Criticisms
Although overall Axios was felt to have been helpful, their internal review process was found to be lacking in insight into the specifics of the Zambian health system. Furthermore, their substantial reporting requirements are only possible with external assistance and have opportunity costs for other reproductive health programmes. It was also reported that they had downplayed the potential drawbacks to using nevirapine – including side effects and resistance – and that they had provided no mechanism for reporting such events.

Comments
Other challenges to the PMTCT programme relate more to the broader policy environment than to the donation programme per se. Critical issues include:

- fostering demand for HIV testing among women;
- encouraging women to deliver in facilities;
- ensuring that babies born outside facilities receive their dose;
- providing sensitive support for women's infant feeding choices; and
- managing the policy transition to dual or triple therapy for those women who may want subsequent access to ART.

To achieve these goals, the programme will need to improve communication with other areas of HIV, reproductive health and child health policy.

Pfizer Diflucan® Partnership Programme (HIV-related infections; cryptococcal meningitis and oesophageal candidiasis)

Country programme background/ assessment of disease in national/district health strategy and plan

It is generally estimated that 10% of patients with AIDS will exhibit cryptococcal meningitis and 30% oesophageal candidiasis. Effective antifungal treatment can improve the survival and quality of life of those affected; prophylactic treatment for cryptococcal meningitis is required for the duration of the patient's life. The recommended first-line treatment for acute cryptococcal meningitis in Zambia is injectable amphotericin B, which can then be followed oral fluconazole.

Programme objectives and strategy in Zambia
In line with the international level programme objectives of making available fluconazole to public sector HIV/AIDS patients with cryptococcal meningitis and oesophageal candidiasis.

Conditionalities
Applications are screened by Axios and a panel of experts on a range of issues including diagnostic ability of prescribers and diagnostic facilities available; health information and inventory management. Approved recipients need to use drugs for the indications within the limitations of the donation, report six-monthly or when re-supply is needed, report diversions and pay for charges after received at the port of entry, permit Pfizer to audit any facility and provide the drug free of charge to the patient.

Nature of partnership (range of partners; partner motivation and objectives)

Programme start date, stage of development, future plans
Start date:

- Through MoH/CBOH: May 2003 (MoU); first consignment and training: June-July 2003
- Through CHAZ: mid-2003; first consignment: September 2003; first training: March 2004

Stage of development:

- MoH/CBOH: 10 facilities: provincial hospitals (nine provinces with two in Copperbelt)
- CHAZ: 11 facilities

Future plans

- MoH/CBOH: through district hospitals and above with roll-out of ARVs
- CHAZ: with roll-out of ARVs (largely to economise on training costs by combining with ART training initiatives)

Governance arrangements:

- Memorandum of understanding signed May 2003

Secretariat/manager: Director Clinical Services, CBOH; assistant to the pharmacy specialist

Dedicated personnel

- National: No dedicated personnel. Day-to-day management at CBOH through assistant to the pharmacy specialist
- Local: Non. Day-to-day management currently with pharmacy personnel managing ART programme

Budget and actual spend; sources of funds
Without money or time limits as long as conditionalities adhered to and for enrolled patients.

Mode of operations
The MOH places orders through Axios, the supplies are delivered to Medical Stores Limited. Utilisation data for all participating facilities is required before an order will be accepted. In practice, facilities tend to only report when there has been significant usage. Obtaining utilisation data for all of the current 10 facilities at the time when an order needs to be made at the national level (to avoid stock outs) is proving to be problematic – there are concerns that when the programme is scaled up to all districts (72) that achieving utilisation information for all the facilities before an order can be made will not be feasible. If there are national stock outs, those facilities reporting regularly will be equally as affected as those not reporting regularly.

Current geographical and epidemiological coverage (e.g. current scale of coverage compared with planned coverage; coverage by socio-economic status, gender, age, rural/urban location)

Whilst the current number of participating facilities is low, it is in line with plans. Other than through the rural CHAZ facilities, only available at provincial urban hospitals. CHAZ reported that the roll out in CHAZ facilities was held up because of a delay in running the training on use and management of fluconazole.

Overall performance against targets to date
No specific information available.

Sustainability measures
As long as the conditionalities are met, the donation is not limited by amount of money or time.

Linkages with other programmes
CBOH and CHAZ are linking the training and roll-out with training on the use and management of ARVs and the roll-out of ART.

Issues
Value-added: Fluconazole would not otherwise be available as it is expensive; the alternate (and preferred) antifungal drug for treatment of acute cryptococcal meningitis (amphotericin B) is also expensive.

Criticisms
Only oral tablets available currently – suspension and IV forms not available yet.

Training costs not met by Pfizer in prescribing fluconazole within the limited indications of the donation or for the programme-specific drug management and reporting requirements; this is a hurdle to the roll-out to a larger number of facilities.

CBOH considers stocks to be low at the central level. It was reported that an order for a new shipment would not be processed until utilisation information is available for all participating facilities, which was seen as a problematic conditionality currently with 10 facilities and would be a major problem if scaled up to 72 (one per district).

Comments
Fluconazole not first-line treatment of acute cryptococcal meningitis in Zambia (amphotericin B will be on the national STG); oral fluconazole will be part of the maintenance therapy. It is unclear how amphotericin B will be purchased.

ANNEX 7

Checklist for compliance with Interagency Guidelines for Drug Donations and price discounts

Checklist for compliance with Interagency Guidelines for Drug Donations, Revised 1999 (WHO/EDM/PAR/99.4)

	DIFLUCAN®	VIRAMUNE®	LEPROSY	LYMPHATIC FILARIASIS SLEEPING SICKNESS
All drugs should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent of the recipient.	Y	Y	Y	Not operational in Zambia
All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national EDL, or, if a national EDL is not available, on the WHO Model EDL, unless specifically requested otherwise by the recipient.	Y (WHO)	Y (WHO)	Y	
The presentation, strength and formulation of donated drugs should, as far as possible, be similar to those of drugs commonly used in the recipient country.	Y	Y	Y	
All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.	Y	Y	Y	
No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.	Y	Y	Y	
After arrival in the recipient country all donated drugs should have a remaining shelf life of at least one year.	Y	Y	Y	
All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.	Y	Y	Y	
As far as possible, donated drugs should be presented in larger quantity units and hospital packs.	Y	Y	n/a	
All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.	Y	Y	Y	
Recipients should be informed of all drug donations that are being considered, prepared or actually underway.	Y	Y	Y	
In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world market price for its generic equivalent.	N	N	Y	
Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.	Y	Y	Y	

Checklist for compliance with Guidelines for price discounts of single-source pharmaceuticals (WHO/EDM/PAR/2003.3)

	COARTEM®	AAI
1. The discount programme should aim to assist countries in promoting access The discount agreement should aim to assist countries in their efforts to achieve equitable and sustainable access to essential health care, including essential medicines. The programme should not be mainly promotional in character, nor should it be designed primarily to increase market opportunities for the company involved to the detriment of others.	Y	Not operating in Zambia
2. The eligible population should be selected on the basis of agreed criteria The countries and patient populations for which the pricing offer is made should be jointly selected on the basis of agreed justifiable criteria, such as health needs, expression of interest, political commitment, economic status, health system infrastructure and potential for sustainability.	Y	
3. The product should be registered for the relevant indication in the country of destination	Y	
4. The medicine should be recommended in a recognised clinical guideline The medicine should offer a cost-effective and safe treatment for the disease, and be recommended by an officially published WHO treatment guideline or included in the WHO Model Formulary. The medicine should preferably be included in a national or organisational treatment guideline and in the national list of essential medicines.	Y	
5. The discounted price should be compared with prices of equivalent medicines The discounted price offered should be compared with the prices of the generic and therapeutic equivalents legally available on the world market.	N	
6. Distribution and other costs should be estimated and funding assured Current and future additional funding requirements for the product and its transport, distribution, training and use should be estimated in advance and the funding should be assured. This also applies to additional costs to national and international organisations involved, such as meeting costs, travel costs and country visits.	*	
7. The scope of the offer should be clearly specified The scope of the discount (e.g. geographical areas, patient categories, products, volume and duration) should be clearly specified. If the discounted price is limited in scope or in time, these limitations must be clearly defined, and the needs of other patients and the long-term sustainability of the programme must be addressed.	Y	
8. Diagnostic and clinical guidelines must be promoted, and treatment facilities available Diagnostic criteria and clinical guidelines for the effective use of the medicine must be defined and promoted. Health workers must have been trained and a supervision system must be in place. Diagnostic and treatment facilities must be available or be developed.	Y	
9. Systems for supply and reporting must be defined The systems for supply, distribution, monitoring and reporting must be defined in advance. These systems should not create an undue burden for all concerned and should, as far as possible, be integrated within existing systems.	Y	
10. The content of the discount agreement should be public Information regarding the content of the discount agreement and the experiences with the programme should be accessible to the public.	Y	

* No information available.

ANNEX 8

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The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop and improve access to health products to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill & Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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